EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF THE MDL 200:	
Betty Funderburke Case No. 2:12-cv-00957	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Patricia Conti Case No. 2:12-cv-00516	
Donna Massey Case No. 2:12-cv-00880	
Amanda Deleon Case No. 2:12-cv-00358	
Wilma Johnson Case No. 2:12-cv-00809	
Harriet Beach Case No. 2:12-cv-00476	
Virginia Dixon Case No. 2:12-cv-01081	

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March 24, 2016

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DEPOSITION OF MARC R. TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.
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March 24, 2016

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Oral sworn deposition of MARC R. TOGLIA, M.D., held at RADNOR HOTEL, 591 East Lancaster Avenue, Wayne, Pennsylvania, commencing at 1:20 p.m., before Margaret M. Reihl, a Registered Professional Reporter, Certified Realtime Reporter, and Notary Public.

A P P E A R A N C E S:

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I N D E X

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E X H I B I T S

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... MARC R. TOGLIA, M.D., having been duly sworn as a witness, was examined and testified as follows ...

BY MR. SCHNIEDERS:

Q. Good afternoon, Doctor.

A. Good afternoon.

Q. My name is Chris Schnieders, and I'm here on behalf of the plaintiff steering committee to take your deposition based upon an expert report that you wrote for a couple of products.

Do you understand that today?

A. Yes.

Q. Would you please state your name for the record.

A. Mark Richard Toglia.

Q. And I believe, Dr. Toglia, that you have given a deposition related to your TVT report already; is that correct?

A. That is correct.

Q. And you understand that we are here today on the Gynemesh PS and Prolift report that you had written?

A. Yes, I do.

Q. Doctor, I'm going to mark as Exhibit 1

the notice that has asked you to come here today and hand it to you.

A. Sure.

(Document marked for identification as Toglia Deposition Exhibit No. 1.)

BY MR. SCHNIEDERS:

Q. Have you seen this document before, Doctor?

A. I have.

Q. And we were talking about this briefly beforehand, but you've brought some documents with you here today; is that correct?

A. Yes, I have.

Q. Okay. I'm going to go through Schedule A, and you just tell me what you brought today that is responsive to those things, and I'm going to ask you some questions on if there are other things that you haven't brought today that are responsive as well, okay?

A. Yes.

Q. Number 1, this is on Page 7, a complete copy of your Curriculum Vitae?

A. I believe that's part of my expert report.

Q. Number 2, "Any and all documents in your possession, including but not limited to, correspondence, notes, videos, CDs, DVDs, flash or USB drives, photographs, databases or materials in other form provided to you or created by you which relate to your opinions, expected testimony or development of your opinions in this litigation."

A. Yes.

Q. Have you brought everything that you believe that you have is responsive in regard to Number 2?

A. Yes.

Q. Number 3, "Any and all documents reviewed by you in preparation for this deposition."

A. Yes, I have.

Q. Okay. And, Doctor, I believe off the record we had discussed the fact that all you've brought with you today are literature that is in your reliance list and your expert reports; is that correct?

A. Yes.

Q. Okay. So you have not reviewed any documents in preparation for your deposition here today that were not in your reliance list?

A. I mean, with the understanding that this

is what I do for a living, there's a tremendous amount of stuff that I do read and review, in general, that's on the subject matter, but I believe that the stuff that's in my report is on the reliance list.

MR. SNELL: Just for clarification, counsel, are you asking about things he's reviewed since his report or depositions of plaintiffs' experts, things like that, because, obviously, those were not available to him at the pertinent time.

MR. SCHNIEDERS: I'm asking for anything at this point with Number 3 that he has reviewed in preparation for this deposition here today.

BY MR. SCHNIEDERS:

Q. Does that cover it, Doctor?

A. Essentially, yes. Understand that I also have access to information that is not published and that I am not at liberty to share because I'm an editor for journals and I review for -- so, obviously, I have not brought that, but I don't quote or cite that information in my report.

Q. Are you relying on any unpublished information --

A. I'm sorry. I'm not relying upon -- sure, I'm not relying upon that information.

Q. Okay. Did you review that information in preparation for your deposition here today?

A. That is information that I have reviewed for my own role outside of this deposition, so not in preparation for this deposition.

Q. Has your counsel been privy to those documents?

A. He has not.

MR. SNELL: I'm not his counsel.

MR. SCHNIEDERS: I'm sorry.

THE WITNESS: I'm sorry. Does that make -- is my intent clear with that?

BY MR. SCHNIEDERS:

Q. Well, if we're going to be clear, I think what you're telling me is that you may have come about information outside of this litigation that has not informed your opinions in this litigation in any way, shape or form, correct?

A. Correct.

Q. And you're not relying upon that information to put forth your opinions in this case, correct?

A. Yes, that's correct.

Q. So is it fair to say that whatever information this is you're talking about, you didn't review it in anticipation for this deposition?

A. Right.

Q. Did you review any depositions that are not on your reliance list?

A. Again, I've got the Ostergard deposition, which I only recently received, so I don't know if that would be on the list or not, but I did bring the deposition with me.

MR. SNELL: Since we're the ones who generated the list, it would not be on there, since the list was -- I took Ostergard's deposition, it was a week or two at least after he produced expert reports, so I do not think it's on there. I haven't even looked.

MR. SCHNIEDERS: Well, and I believe, counsel, did we receive a new reliance list yesterday.

MR. SNELL: It wasn't a new reliance list. It was, essentially, a corrected one. I think the paralegals attached his sling TVT reliance list to both his TVT report and his

prolapse report, instead of attaching the right prolapse list to the prolapse report. So it's not amended or updated or anything like that. It's just they stuck the wrong one on the POP report.

MR. SCHNIEDERS: Okay. So the list that was produced yesterday was the list as of the date of the issuance of the report?

MR. SNELL: Like 29th to 30th of February.

MR. SCHNIEDERS: And did you bring a copy of that list that was produced yesterday because I don't know if I have that list to mark as an exhibit here today.

MR. SNELL: Do you have a copy?

THE WITNESS: This, POP?

MR. SNELL: If you want to take that, you can mark it.

MR. SCHNIEDERS: We'll get to that in a second.

MR. SNELL: But as to your question, I doubt Ostergard's deposition was on this, I don't see it on here.

BY MR. SCHNIEDERS:

Q. Doctor, have you reviewed any documents since your deposition on the TVT report that you hadn't previously reviewed before the TVT report deposition?

MR. SNELL: Form.

THE WITNESS: Yes, the information as it relates to Gynemesh and Prolift were not part of my TVT report.

BY MR. SCHNIEDERS:

Q. But you issued those reports at the same time, didn't you?

A. No. This report was issued February 26, 2016. The other report was issued back in October.

Q. Okay. Doctor, have you brought -- strike that.

You haven't brought -- are there any photographs or other images including photographs of the plaintiffs, the plaintiffs' explanted mesh or products taken by you or for you which relate to your opinions in this case?

A. No.

Q. Have you brought any Ethicon products in your possession?

A. I don't have any Ethicon -- oh, Ethicon products, no.

Q. "Any and all documents, including time sheets, invoices, time records, billing records which record or document the work performed, time spent or charges made in connection with your expert opinion in this matter."

A. I have my invoices, yes.

Q. And are they here today?

A. I'm sorry. What is the date of the last invoice? There should be a date end of February.

Q. Yeah, there's a February 29th of this year.

A. Right.

Q. Is that the most recent invoice?

A. Most recent invoice that I have submitted, correct.

Q. Any communication between you and your counsel -- I'm sorry, strike that.

Any communication between you and counsel for the defendants, to the extent such communications relate to your compensation; identify facts or data that you were provided and that you considered in forming your opinions; or identify assumptions that plaintiffs' counsel provided you and that you relied on in forming your opinions.

A. No.

Q. How have you communicated with defense counsel in this case?

A. By phone.

Q. Have you ever e-mailed with defense counsel?

A. Not an opinion or the stuff that you just referred to, no.

Q. So nothing about compensation rates or bill sheets or anything like that?

A. No.

Q. Did you collect a retainer in this case?

A. I did not.

Q. Do you typically collect retainers in cases in which you --

A. I do not.

Q. And if you let me finish my questions, I'll let you start off after that, if you don't mind, because otherwise we'll get on top of each other.

So, as I sit here, I've got two invoices that are dated January 31st of 2016 and February 29th of 2016, and that is all of the time that you have billed to date in the Ethicon Gynecare mesh litigation titled MDL 200? I'm just reading off of this.

A. That is everything I have billed to date.

Q. When were you first contacted to work in this case?

A. End of August 2015.

Q. All right. Moving through the notice to get through that, Number 10, any and all documents, including consulting agreements, time sheets, invoices, time records, billing records which record or document the work performed, time spent or charges made in connection with consulting related to studies, consulting work, cadaver labs, professional education training and any other work that has been compensated by defendants or expert fees charged to defendant related to any female pelvic mesh product sold by Ethicon for treatment of stress urinary incontinence or pelvic organ prolapse.

Did you bring any documents related to Number 10?

MR. SNELL: I'll just note for the record, I think we filed objections as to some of these requests. Go ahead.

THE WITNESS: I don't believe we've provided any of that.

BY MR. SCHNIEDERS:

Q. Have you provided any of that to defense counsel?

A. I don't have an independent recollection that I have.

Q. Whether you have provided it to defense counsel or not, do you have documents that would fall under category 10?

A. I don't have documents. If I'm not mistaken, at the TVT deposition we did cover the amount and extent of my participation and compensation from Ethicon.

Q. I appreciate that, Doctor, but as far as the documents that have been requested here at Number 10, do you have any responsive documents in your possession?

A. Like I said, they were covered in the TVT deposition, that's all. That's all I have.

Q. You produced all the documents you had in your possession as part of the TVT deposition?

A. I don't recall the specifics, but I do recall that we went over all that on record, correct?

MR. SNELL: Yeah, I think he did produce whatever he had.

THE WITNESS: Right.

MR. SNELL: I think this is the same as what he produced -- whatever he had, he produced.

THE WITNESS: Right, yes.

BY MR. SCHNIEDERS:

Q. So you produced consulting agreements?

A. I don't know the answer to that. I don't recall.

Q. Do you have consulting agreements with Ethicon?

A. None actively, no.

Q. Do you have the paper that reflects the consulting agreement with Ethicon?

A. No, I do not.

Q. You don't keep any of those for your files?

A. No.

Q. Do you keep records of your invoices that you send to Ethicon?

MR. SNELL: Object to form. Go ahead.

THE WITNESS: I don't have the records, no. I haven't done consulting with Ethicon in years, and I discard such things after usual

tax, it might be five years, I can't remember, three to five years I discard them.

BY MR. SCHNIEDERS:

Q. Just so we're clear on the record, right now we're talking about things that are outside of litigation, correct?

A. Understood.

Q. And so when is the last time that you consulted outside of litigation with Ethicon?

MR. SNELL: Object. This is covered in his first deposition, but go ahead.

THE WITNESS: It's to the best of my recollection, and it is a guesstimate at best, 2011. It's not been -- not in my working memory.

BY MR. SCHNIEDERS:

Q. Do you recall in the last six months destroying any of these kind of documents?

A. No, I did not.

Q. So is it your testimony here today that you have no documents that are responsive to Number 10 in your possession that you have not previously produced as part of your TVT deposition?

A. Yes, it is.

Q. Is that because the documents are all in the possession of your practice?

A. I don't believe they are.

Q. Okay. Well, if we go back, Doctor, and see from the TVT deposition that there wasn't anything produced that's responsive to Number 10 from you, are there responsive documents somewhere that you have?

A. I think I've answered that. I do not have what you're asking for in my possession, because I have not had any active consulting agreement with Ethicon for more than five years. I certainly have not destroyed anything since I was contacted by Mr. Snell regarding these matters.

Q. And you were contacted in August of 2015?

A. I believe so.

THE WITNESS: Does that sound right to you?

MR. SNELL: I can't testify, but I think you're in the right ballpark.

THE WITNESS: Okay.

MR. SNELL: And this is to the best of your recollection.

THE WITNESS: To the best of my

recollection.

BY MR. SCHNIEDERS:

Q. How were you contacted by Mr. Snell?

A. Telephone.

Q. Did you know Mr. Snell prior to that conversation?

A. No, I did not.

Q. Did you know any of Mr. Snell's partners prior to that?

A. No, I do not.

Q. Had you ever worked on a legal case prior to Mr. Snell contacting you?

MR. SNELL: Form.

THE WITNESS: I had worked on malpractice cases but not product liability cases.

BY MR. SCHNIEDERS:

Q. So you served as an expert witness in a medical malpractice case before?

A. I have.

Q. We'll talk about that in just one moment.

MR. SNELL: Counsel, this was all covered in depth in the TVT deposition.

MR. SCHNIEDERS: Taking my deposition, Burt, you can talk about whatever you want. They're responsive questions.

MR. SNELL: Actually, no, you're not, because the parties have an agreement; there shall not be duplicative discovery of experts.

MR. SCHNIEDERS: I've looked through the entire transcript, and I'm very comfortable that I'm asking the right questions, not to mention the fact that you've given me a whole other reliance list that I got yesterday, so I've got to ask my questions and see what's out there. There weren't any consulting agreements produced as part of the TVT deposition.

MR. SNELL: I know that because he didn't have any, but I think he told you they were marked. They were definitely discussed in that deposition. I don't have the deposition with me, but I know for a fact that they were marked.

MR. SCHNIEDERS: Well, I just read it again last night so -- and those consulting agreements would have been there and, okay, you can look at what's been marked in there, if you

have the transcript. There weren't any.

MR. SNELL: I don't have the transcript with me.

MR. SCHNIEDERS: Okay. Let's not waste time on it, all right.

BY MR. SCHNIEDERS:

Q. Number 11, "Copies of Schedule C and Form 1099 of your tax records for the preceding five (5) tax years, as well as any other documentation that reflects consulting and/or expert fees charged to defendants (with personal information and any other information unrelated to consulting fees redacted)."

MR. SNELL: We objected to that, and this witness will not be producing his tax forms.

MR. SCHNIEDERS: And what's the basis of that objection?

MR. SNELL: Invades his privacy, all the bases we set forth. Your experts have not produced any of their tax forms.

BY MR. SCHNIEDERS:

Q. Number 12, "All correspondence, memoranda, e-mails and/or any other documentation reflecting communications (including written,

electronic and/or oral) with any employees of defendants related to any female pelvic mesh product sold by Ethicon, Inc. for treatment of stress urinary incontinence or pelvic organ prolapse."

Have you produced any such correspondence, memoranda, e-mails or other documentation, Doctor?

A. I believe I answered earlier that I don't have any of those correspondence in my possession.

Q. What's your current e-mail address?

A. I think that's personal information. That's not a question I'm willing to answer on the record.

Q. Is it @ATT.net address?

A. I'm not going to answer that question.

Q. Is that on counsel's instruction or on your own volition?

A. I don't see how that's relevant to my role. I'm here to discuss my expert report and my opinions in that regard.

Q. In your communication with sales representatives for the defendant, did you ever use your personal e-mail address?

MR. SNELL: I'm going to object. This

is irrelevant. This is, I think, covered in the first deposition, and you're about to get into areas that -- well, we'll leave it at that.

MR. SCHNIEDERS: I think I know what you're talking about, and I don't intend to go anywhere near that, so you can relax on that.

THE WITNESS: I'm not trying to be obstructive or difficult, but to the best of my knowledge, I don't recall ever using personal e-mail to respond -- well, I don't, I don't. I don't remember. I don't recall.

BY MR. SCHNIEDERS:

Q. I'll be fair to you on this, Doctor. I'm not trying to elicit some of what I think you're thinking I'm trying to elicit right now.

A. I understand.

Q. In your first deposition there were some e-mails where you did, and I'm not talking about any specific instance, but there were e-mails back and forth with other people that are involved in Ethicon in their professional capacity?

A. Correct, right, okay, correct. But I don't have in my possession any of that, those

transcripts, I don't have any copies or -- I don't have copies of those e-mails. I haven't used an AT&T address in I don't know how long.

Q. And did -- with your new address which I've also seen on some e-mails, did you go back when you received this notice to review to see if you had any responsive e-mails?

A. I did not have any responsive e-mails.

Q. You looked for them?

A. Yes. The last -- I mean, the last communications I had with Ethicon had nothing to do with any of the stuff that we're discussing today. They were on projects that were unrelated to any of this.

Q. What projects?

A. They were projects for other products that are not related to Gynemesh or Prolift.

Q. Okay. They were other products that were made or in production or premarket by Ethicon?

A. They were concepts for potential products within this sphere of female pelvic floor disorders.

Q. Like the Sphinx?

A. Correct.

Q. Any others?

A. No, no.

Q. And the Sphinx never made it to market, correct?

A. It never made it past the conceptual stage. Does that make sense to you?

Q. It does.

A. Okay.

Q. Number 13 is duplicative of some of the other ones. I'm assuming you are going to tell me that you have produced everything that is responsive to Number 13; is that correct, Doctor?

A. That would be my position, correct.

Q. Number 14, "All documents related to deponent's involvement with Ethicon's professional education, including, but not limited to any and all PowerPoints, course materials, outlines, videos or presentations, live surgical presentations, marketing evaluations created by or provided to deponent related to any female pelvic mesh product sold by Ethicon, Inc. for treatment of stress urinary incontinence or pelvic organ prolapse.

Do you have any responsive documents to Number 14?

A. I do not have any of those items in my possession.

Q. You didn't keep any PowerPoints or anything you put together?

A. No. To be clear, I never created any of those talks. There were talks that might have been provided to me. Once my consulting arrangement changed and I threw things out, I don't really keep that stuff.

Q. They were provided to you by Ethicon, right?

A. Products related, right. I mean, I think some of them we have -- we have brought, the Prolift professional education materials. Nothing different than that.

MR. SNELL: Right, but I think he's asking you did you have -- do you have any from back when you were a consultant, not stuff that you reviewed and prepared that's on the thumb drives.

MR. SCHNIEDERS: Right.

MR. SNELL: I think that's what he's asking about.

MR. SCHNIEDERS: That's correct.

THE WITNESS: No, I don't have it.

BY MR. SCHNIEDERS:

Q. Just so we're clear on the record here, Doctor, you've given talks on behalf of Ethicon, right?

A. Correct.

Q. You've used presentations in those talks at times like PowerPoints, right?

A. That were provided to me by Ethicon.

Q. And those were put together by Ethicon for you to present?

A. Correct.

Q. And you don't have any of those in your possession, as we sit here today, correct?

A. I do not.

Q. Okay. Number 15, "Any and all materials including, but not limited to, protocols, results, adverse events, minutes for study meeting related to any clinical trials and/or studies of any type related to deponent's work as consultant for defendant in any capacity related to any female pelvic mesh product sold by Ethicon, Inc. for treatment of stress urinary incontinence or pelvic organ prolapse."

Do you have any responsive documents, Doctor?

A. I do not.

Q. Are you currently involved in enrolling

in a clinical trial?

A. I am not.

Q. So just so we're clear, anything that is responsive to Number 15 you've either produced or don't have anymore, correct?

A. Correct.

Q. "16. Any reports/documents, whether kept in hard copy or electronic form, relating to any other matter involving any female pelvic mesh product for treatment of stress urinary incontinence or pelvic organ prolapse."

Do you have any responsive documents to Number 16, Doctor?

A. I do not.

Q. You don't keep anything on any other female pelvic products?

A. I do not.

Q. "Any and all documents, including transcripts or statements, between you and any governmental agency regarding any female pelvic mesh product used for treatment of stress urinary incontinence or pelvic organ prolapse."

Do you have any responsive documents to Number 17, Doctor?

A. I do not.
Q. Have you ever reported an adverse event to the FDA?
A. I have.
Q. Do you ever keep a record of that?
A. No.
Q. Have you ever reported an adverse event related an Ethicon product to the FDA?
A. I have.
Q. On how many occasions?
A. I don't know the answer to that.
Q. Ballpark, ten?
A. Ten may be a reasonable guess.
Q. Have you ever reported any adverse events to the FDA for any of the products we're here to talk about today?
A. I have.
Q. Can you tell me which products?
A. Prolift, I'd say three or five.
Q. Any for Gynemesh PS?
A. No.
Q. Any for TVT?
A. Not that I can specifically recall.
Hold on.

In all honesty, most of the reports that I have filed with the MAUDE probably involved non-Ethicon products.

Q. Any particular reason?

A. I think that they reflect what -- these were not products that I personally had implanted, but they were women that I subsequently cared for, and it just simply reflects the nature of my referral practice.

Q. Because as a physician, you have a duty when you find out about an adverse event to report it, regardless of how you come about that information, right?

MR. SNELL: Objection, calls for a legal conclusion.

BY MR. SCHNIEDERS:

Q. Was that a yes, Doctor?

A. I have reported events that I have come across as a surgeon.

Q. And my point is just that regardless of whether or not it's your patient or you find out about it from another manner, you would still report an adverse event because you have a duty as a doctor to do that, correct?

MR. SNELL: Objection, calls for legal conclusion.

THE WITNESS: I'm not so sure about the duty, but my personal practice is to report those events.

BY MR. SCHNIEDERS:

Q. And it's fair to say that with regard to types of mesh products that we're talking about here today, and I'm talking about the entire spectrum, regardless of Ethicon or other manufacturers, that you've reported more adverse events for the other manufacturers than Ethicon?

MR. SNELL: Form.

THE WITNESS: I would say that is likely true.

BY MR. SCHNIEDERS:

Q. Do you have any recollection of what product you've likely reported the most times as an adverse event?

A. I do.

Q. Which product is that?

A. I believe Apogee Perigee.

Q. Do you have any idea of how many adverse events you reported on that product?

A. I do not.

Q. Number 18 says, "Any and all documents relating to an presentations, PowerPoints or lectures regarding any female pelvic mesh product used for treatment of stress urinary incontinence and pelvic organ prolapse."

Is your answer the same as it was regarding the materials themselves that you don't have anything in your possession?

A. That is correct.

Q. Lastly, Number 19, "Any demonstrative exhibits, such as graphics or charts, prepared by or on your behalf for use at trial."

Do you have any responsive documents?

A. We're talking about other than what has already been provided either in my TVT deposition or currently?

Q. Yes.

A. I have nothing in addition.

Q. You can set that to the side.

MR. SCHNIEDERS: I'm going to do a little housekeeping here because I actually premarked a few things, and I'm going to get off track if I don't do it the right way.

(Document marked for identification as Toglia Deposition Exhibit No. 2.)

MR. SCHNIEDERS: I'm going to hand you your CV, which I've marked as Exhibit 2.

BY MR. SCHNIEDERS:

Q. Doctor, this looks like this was revised at the top right there on 8/13 of 2015; is that correct?

A. Yes.

Q. Is this your most current CV?

A. Yes.

Q. Doctor, you are what's called a urogynecologist, correct?

A. Actually, I am a specialist in female pelvic medicine and reconstructive surgery, which was formerly referred to as urogynecology.

Q. I see in 2013 that you went to get a board certification in female pelvic medicine and reconstructive surgery.

Can you tell me what that entailed?

A. I didn't go in 2013. I went in 2012 and in 2013 I received certification. So female pelvic medicine and reconstructive surgery is the fourth subspecialty within the specialty of obstetrics and

gynecology. It is duly accredited by both the American Board of Obstetrics and Gynecology and the American Urologic Board.

This involved -- this is a multipart process culminating in taking and passing a written exam. Prior to that, there were demonstration of adequate case volume and level of training. For example, you had to be previously board certified either by the American Board of OB-GYN in OB-GYN or the American -- the ABU, the American Board of Urology.

Q. And was that a facility locally that you were able to go and do some of this work, or how did that actually work out?

A. Well, the process is guided by the ACGME, the American College of Graduate Medical Education. The exam itself was taken via computer by local sites throughout the country, locally through some of the different learning centers.

Q. Prior to 2013 when you received the board certification and began your work, did you consider yourself to be a specialist in the area of female pelvic medicine and reconstructive surgery?

A. That's correct.

Q. How many people nationwide hold this

subspecialty, if you know?

A. So in 2013 approximately 750 of us were board certified, and 2014/2015 there might have been the addition of another 100 or so each year. I couldn't give you the final number. I'm sure it's something that's readily available, but I'm going to guesstimate we're talking about 1,200 individuals who are currently board certified in the subspecialty.

Many others, including some of your experts, did not sit for the boards, but this is still their area of expertise and practice.

Q. Did any pharmaceutical company or device company in any way, shape or form fund or help with your board certification?

A. No, none whatsoever.

Q. They didn't sponsor any programs that had to do with it?

A. No.

Q. Do you have any academic appointments, Doctor?

A. I do. They're listed on my CV.

Q. And when I say that, are you employed by any of these facilities?

A. I am not.

Q. Do you teach any classes?

A. I teach clinically, I give lectures. I don't teach classes in the sense that a college professor would teach classes.

Q. On Page 2 and, obviously, you know your CV so you probably don't need it to talk through it, but I see that you're a member currently of some professional societies. I think I know which ones they are, but there was a couple typos later on, so I just want to make clear which of these professional societies are you currently a member of?

A. Sure. I'm currently a member of the American Urogynecologic Society, the Society for Gynecologic Surgeons, the International Urogynecology Society, which is not on this list, I don't think. I'm a fellow of the American College of Obstetrics and Gynecology as well.

Q. Okay. And moving to the next page, it appears that you hold or at least held as of 2015 a vice chair position for the Committee for Government Relations and Coding at the American Urogynecologic Society; is that correct?

A. I'm currently the chair of that committee.

Q. Okay.

A. And it's actually the chair of coding.

Q. Okay. And in your position as vice chair and now chair, what are your duties?

A. I represent the society nationally at meetings such as the CPT, the RUC. I interact directly with the government through CMS. I represent the society as a liaison member to the American College of Obstetrics and Gynecology, and I either head or direct certain task forces as they relate to coding and health economics within the sphere of female pelvic medicine.

Q. Okay. And if I say AUGS, you know what I'm talking about, right?

A. I do.

Q. So your position as vice chair, then chair of this committee with AUGS is tied to this bottom one here, where it says "Member, ACOG Committee of Health Economics and Coding, AUGS Liaison"?

A. Yes.

Q. Okay. Tell me what AUGS is.

A. AUGS is a professional organization of healthcare providers, which includes physicians, physical therapists, nurse specialists that are interested in promoting excellence in female pelvic

medicine and reconstructive surgery.

Q. Is it sponsored by any pharmaceutical or device companies?

A. It is not.

Q. What about ACOG, tell me what ACOG is.

A. ACOG is the professional organization, it's the American College and Congress of Obstetrics and Gynecology that is based out of Washington, DC and comprises the professional members, again, doctors, nurse practitioners, other healthcare providers in the specialty of obstetrics and gynecology.

Q. Okay. And is ACOG sponsored or funded by any pharmaceutical or device companies?

A. No.

Q. And you're sure about that with regard to AUGS and ACOG?

A. I am certain about that.

Q. Down here under Hospital Service it says, "System Chief, Division of Female Pelvic Medicine and Reconstructive Pelvic Surgery, Main Line Health."

What is Main Line Health?

A. Main Line Health is the largest health system here in Philadelphia. It's a not-for-profit system consisting of four hospitals.

Q. And do you have privileges at all four of those hospitals?

A. I have privileges at all four hospitals.

Q. Is there any particular hospital you do the majority of your procedures at?

A. Yes.

Q. Which one is that?

A. I split my time clinically between Paoli Hospital located in Paoli, Pennsylvania and Riddle Hospital located in Media, Pennsylvania.

Q. If you want to move on, Doctor, to Page 4, there is a section at the bottom there that's called "Past Clinical Research Projects."

Do you see that?

A. I do.

Q. And it looks to me as if there are nine times in your past in which you've participated in a clinical study; is that correct?

MR. SNELL: Hold on. Did you say nine?

MR. SCHNIEDERS: That's what I see, because I'm skipping ten, so I'm going to ask him separately.

MR. SNELL: I'm going to object to form.

BY MR. SCHNIEDERS:

Q. You tell me, because ten seems to be a bit different, because I asked you earlier if you were in the process of enrolling patients, and you told me no. So let's just start with 1 through 9. It looks like there were several clinical research projects you were involved with?

MR. SNELL: I'll just note for the record this issue in Number 10 and the statement about currently enrolling patients I know was covered in his prior deposition.

MR. SCHNIEDERS: I'll let you make your objections. If I can finish my questions before you start them, if you don't mind.

MR. SNELL: Go ahead. Covered.

BY MR. SCHNIEDERS:

Q. So, Doctor --

A. I've participated in ten, and I am not currently enrolling.

Q. Okay. And tell me why that is?

A. Because this is simply a typographical error, and that was covered in my deposition with the TVT trial. And my apologies, the problem is I can't make corrections because these belong to the Court. If I had another copy, I'm happy to correct that for the

next time, but I realize this comes up, but I don't have my own set of private things that I can correct these things on, but I will tell you that that is an old trial that has already been published.

Q. And that's my question, Number 10 then, is that the actual trial that you did go on to publish?

A. Yes.

Q. That's listed as Number 23 under your publications?

A. Yes.

Q. Doctor, other than 23, are there any publications that you have ever made with regard to any mesh product?

MR. SNELL: Form.

THE WITNESS: Twenty-four is an editorial that I wrote that talked about sacrocolpopexy, which would involve the mesh, but that is an editorial.

BY MR. SCHNIEDERS:

Q. But no other articles other than those two?

A. Article 16 was a study I published with my own patient population. Some of those patients did have a mesh procedure, although, to the best of my

knowledge, we did not stipulate what that was.

Q. But fair to say that that article was primarily about polyester sutures?

MR. SNELL: Form.

THE WITNESS: As the title suggests, it was about both long-term surgical outcomes as well as wound complications in that population.

BY MR. SCHNIEDERS:

Q. All right, Doctor, I'd like to switch topics now, and I'd like to start with your first work with Ethicon.

It's my understanding that you were recruited by Dr. Lucente; is that correct?

MR. SNELL: Objection, asked, and this is all covered in his first deposition.

THE WITNESS: No, I was not recruited by Dr. Lucente.

BY MR. SCHNIEDERS:

Q. Well, how would you characterize it?

MR. SNELL: Objection, asked and answered, prior covered.

THE WITNESS: How I was contacted by Ethicon?

BY MR. SCHNIEDERS:

Q. Yes.

A. I don't recall the specifics. I would have been contacted probably by a product manager.

Q. Approximately what year would that have been?

MR. SNELL: Same objection. This is all covered in the prior deposition.

THE WITNESS: 1999.

BY MR. SCHNIEDERS:

Q. Okay. Had you ever worked for Ethicon prior to being contacted for that consulting?

A. That was the first contact.

Q. Okay. Prior to 1999 had you worked with other pharmaceutical or device companies?

A. I think I had, yes.

Q. Which companies had you worked with prior to working with Ethicon?

A. Well, I did clinical trials for what we then called Yamanouchi, which is now called Astellas. I did a clinical trial with Eli Lilly, a clinical trial with Pfizer.

Q. Pharmacia?

A. I did some work with Johnson & Johnson, which owns Ethicon, but at the time it was not with

Ethicon, I don't believe, no. Realize this is not directly relevant, but whether or not Monistat as a product was Ethicon versus Johnson & Johnson, I don't know.

Q. But that was the product at that time?

A. Correct.

Q. Aside from what's listed in your past clinical research projects and the companies that you've listed as the sponsors, do you recall any other pharmaceutical companies you worked with prior to 1999?

A. Yes, there were a host of them.

Q. Which ones can you name for me?

A. Now you're really taxing my long-term memory. Rhone-Poulenc Rorer. As you probably are aware, counselor, many of these companies have been absorbed and renamed.

Q. That is Aventis now, that would be Aventis?

A. Right, correct. Pharmacia Upjohn, that's probably it.

Q. Other than the ones that are listed in your CV, that would be about it?

A. Correct.

Q. Okay. Starting in 1999, what was your

work with Ethicon?

MR. SNELL: Objection, form and covered in prior dep.

THE WITNESS: I think I previously stated that initially I may have participated in some kind of market research that actually probably was prior to '99, let's say '98. I don't necessarily consider that a consulting relationship. I was just asked to give feedback from a marketing perspective on the TVT product. At some point in time, I started to get involved more in the professional education teaching, the TVT technique.

Does that answer your question?

BY MR. SCHNIEDERS:

Q. Sure, that's the beginning. So as a preceptor, correct?

A. Correct. And I also started to serve in an advisory or a consultant role.

Q. What products did you serve as a preceptor for with Ethicon?

A. I would say the TVT family of products, TVT, TVT obturator, TVT Secur, TVT Abbrevo, TVT Exact.

Q. Did you ever serve as a preceptor for

Gynemesh PS?

A. To the best of my knowledge, no.

Q. Same question with regard to Prolift?

A. Yes.

Q. Have you ever served as a preceptor for any company that was not Ethicon?

A. I don't believe so.

Q. So your relationship with Ethicon would have began with a market research consulting or whatever you want to call that in 1998 and, based upon your recollection, continued till about 2011?

MR. SNELL: Object to form, previously covered.

THE WITNESS: I believe so, yes.

MR. SCHNIEDERS: I'm going to switch topics. Does anyone want to take a break, or are we okay?

MR. SNELL: Take a five-minute break.

(Brief recess taken at 2:09 p.m.)

(Deposition resumes at 2:14 p.m.)

BY MR. SCHNIEDERS:

Q. Doctor, we're back after a short break. In your current practice, Doctor, what surgeries do you perform for stress urinary

incontinence?

A. Currently, we perform a combination of midurethral slings, such as TVT Exact, TVT Abbrevo. We perform periurethral bulking procedures, autologous fascial slings, retropubic urethropexies.

Q. And are there any slings that you use aside from TVT products?

A. There are not.

Q. Have you ever used any sling aside from a TVT product?

MR. SNELL: Objection.

BY MR. SCHNIEDERS:

Q. Strike that. Have you ever used any sling aside from an Ethicon product?

MR. SNELL: Form, previously covered.

THE WITNESS: Yes.

BY MR. SCHNIEDERS:

Q. What products have you used in addition?

A. Boston Scientific, Advantage Fit, AMS RetroArc. Cook had a biologic sling, Surgisis ST, don't quote me on the trade name on that one. I think that's it.

Q. Fair to say the vast majority of the slings that you've put in have been TVTs?

A. I would say 99%.

Q. What nonsurgical remedies are you using for women suffering from stress urinary incontinence currently?

A. Currently, we use biofeedback, electrical stimulation, pelvic floor muscle therapy. We actually have a physical therapist within the practice for that. Previously, as you can see from my CV, we were involved in the Duloxetine trial. Occasionally, we will use barrier type devices.

Q. When a woman comes into your office with stress urinary incontinence, what's your first line treatment?

A. Well, first line treatment starts with education, pelvic floor muscle exercises, behavioral modification, fluid management.

Q. What current surgeries do you use for pelvic organ prolapse?

A. Again, this is what I do for a living. There's a wide breadth of procedures that we do either abdominal, vaginal, with or without hysterectomy, native tissue plications, graft augmentation, specifically abdominal sacrocolpopexies, obliterative procedures such as colpocleisis,

c-o-l-p-o-c-l-e-i-s-i-s.

Q. What nonsurgical remedies do you use?

A. Again, we will use physical therapy, pelvic floor muscle rehabilitation, pessaries.

Q. Do you currently use the Gynemesh PS?

A. I do.

Q. How often would you say you currently use the Gynemesh PS?

A. Two days a week.

Q. And is that two surgeries a week, or is that on two days you use it several times?

A. Two days a week I typically do between six and eight surgical procedures a week for incontinence or prolapse.

Q. Okay. And specific to Gynemesh PS, how often are you using that?

A. I use it two days a week, as I mentioned, perhaps maybe half my surgical repairs, maybe 40%.

Q. 40% of surgical repairs of POP?

A. For prolapse. It varies obviously.

Q. How many pelvic organ prolapse surgeries would you estimate you have performed as a surgeon?

A. Thousands. I've been in practice for

nearly 25 years. I have an annual surgical load that varies probably between 150 and 200 surgical procedures a year.

Q. And how many times do you believe or would you estimate that you used Gynemesh PS for the surgery?

A. I believe that's in my surgical -- excuse me. I believe that's in my report. Off the top of my -- I just want to verify it. Off the top of my head, I believe it was 3,000, approximately 3,000 within our practices.

Q. And that's specific to Gynemesh PS?

A. I believe so. I mean, it's Gynemesh and related materials.

Q. Well, I'm going to ask, so how many Prolifts?

A. Prolifts probably number 200 or more.

Q. You say "and related materials," are you including the Prolift within that 3,000 for Gynemesh?

A. I'm sorry, let me try to be more clear. I'm talking about specifically macroporous polypropylene graft material, which would include Gynemesh PS, Prolift predominantly.

Q. Can you explain how that mesh differs

from the TVT mesh?

MR. SNELL: Form.

THE WITNESS: Yes, I mean, they're both type 1 polypropylene mesh. I believe I covered this in my report. There are differences in terms of both weight and pore size.

BY MR. SCHNIEDERS:

Q. And what are the differences in weight and pore size?

A. Again, I believe I've covered that in my reports. Approximately, Gynemesh PS is going to be about 42, 43 grams per meter squared. It's got a pore size of about 2,400 microns.

The mesh used for TVT is approximately twice that. I believe the mesh is probably in the neighborhood of 90 grams per meter squared. The pore size is probably around 1,200 microns.

Q. You said 2,400 microns for Gynemesh?

A. 2.4 millimeters is the pore size.

Q. Doctor, do you keep track of any complications you have with your mesh surgeries?

A. Yes.

MR. SNELL: Form, asked and answered earlier.

BY MR. SCHNIEDERS:

Q. How do you keep track of that?

MR. SNELL: Same objection.

THE WITNESS: Are you allowing me to answer?

MR. SNELL: You can go ahead and answer. I mean, it's all in the report.

THE WITNESS: It's changed throughout the years. Currently, our patients are enrolled in a national registry prospectively, where we keep track of all prolapse surgery.

Previously, we would use private databases. Obviously, we have medical records in our office. We have electronic health records in our system. I've been in the same practice now for 19 years.

BY MR. SCHNIEDERS:

Q. Okay. And you keep track of all those numbers?

A. The records are all available to us. We review them periodically as we go on.

Q. When you say "periodically," who are "we"?

A. I guess you're looking at we. We would

be me. It would be me, my partners.

Q. How many partners do you have?

A. I currently have one physician partner and one nurse practitioner partner.

Q. And does your nurse -- or I'm sorry, your physician partner, does she review those along with you?

A. My current partner who has been with me less than two years has not. My previous partner had.

Q. And when you review the data that you have in your office regarding how many you've put in, what kind of report, if anything, do you output as a result of that?

A. It depends. I'll offer as an example, you know, my partner at the time Dr. Fagan and I published the article that we spoke of earlier, in which we, from the database, reviewed nearly 100 women that had undergone prolapse surgery using a specific technique sacrospinous ligament suspension, and we looked at outcomes, we looked at complications, recurrences, re-operations. So temporally we may stop and look at what we've been doing to better understand what the limitations and successes are of those procedures.

Q. Okay. And do you reduce what you look at to any sort of a tangible form that you can share with the company or other physicians?

MR. SNELL: Object to form.

THE WITNESS: I wouldn't share anything with a company. It has nothing to do with a company. It varies. Sometimes we review it internally and we do nothing with it. Sometimes we publish it, sometimes we present it. Sometimes this is done as part of a larger consortium of researches, such as the TVT Secur. Obviously, the prospective registry database is something that we contribute to. I guess in that regard my current partner and I contribute to that database together. Someone else is analyzing that, so it just varies.

BY MR. SCHNIEDERS:

Q. Do you keep track of complications as a result of your database?

A. Yes.

Q. And do you review those periodically as well?

A. Yes.

Q. When is the last time you looked at

that?

A. Yesterday.

Q. Forgive me, Doctor, but when you look at this, what are you looking for? Are you just looking at straight numbers? What is it that you're seeing?

A. It depends upon the clinical question that at the time we're interested in looking at. It's, you know, currently we've been looking at voiding function following midurethral slings in our patients, how they are at, say, one month. You know, we'll look at our rates of retention, need for revision, things like that.

Q. Do you have a number of women that needed revisions that you implanted mesh in?

MR. SNELL: Form.

THE WITNESS: It's a very, very small number.

BY MR. SCHNIEDERS:

Q. Well, let me ask you this, Doctor: Can you tell me how many revisions you've performed in your career?

MR. SNELL: Object. I think this was covered in prior depo.

THE WITNESS: It was.

MR. SNELL: You can go ahead and answer the question. Let me try and pull up the transcript.

THE WITNESS: I don't have that in my working fund of knowledge. It's essentially on an annual basis and, again, understand that more the revisions that I do are not patients that I was the implanter so -- but it's about 1 to 2%.

BY MR. SCHNIEDERS:

Q. One to 2% of your --

A. Of those I implant, correct.

Q. And I've seen you testify on this particular issue before, and you stated that it's your belief that it's physician error when there's a complication; is that correct?

MR. SNELL: I'm going to have to object. I think you may have misstated his testimony.

MR. SCHNIEDERS: Well, he can certainly tell me that, if that's the case.

MR. SNELL: -- in its entirety. Why don't you show it to him then, because I don't know what you're talking about, to be honest with you.

MR. SCHNIEDERS: I'm asking him a question. If he says I'm not stating it right, then please do, Doctor. I'll ask the question again.

THE WITNESS: You're asking me a question, and I'm more than happy to answer, but you're not providing me with the foundation or the reference.

BY MR. SCHNIEDERS:

Q. Okay. Let me ask it this way: Do you believe that when there is a mesh complication that it is the result of physician error?

MR. SNELL: Form, overbroad.

Are you talking sling, prolapse or anything?

MR. SCHNIEDERS: I'm asking a question.

MR. SNELL: So overbroad.

THE WITNESS: Would you be okay with substituting operator dependent for physician error? I don't know that I'm not comfortable with the term "physician error." I mean, I think it's operator dependent, rather than material related.

BY MR. SCHNIEDERS:

Q. Okay. That's fair.

So to put it in simpler terms, it's the result of something that was or was not done by the physician, not saying it was negligent or anything like that?

A. I understand.

Q. That was the variable, not the material, correct?

MR. SNELL: Same objection, overbroad.

THE WITNESS: So --

MR. SNELL: Vague as to time and scope.

Go ahead.

THE WITNESS: So the background is simply, you know, you've got the surgeon, you've got the patient, and the patient certainly -- the risks for something like retention varies based upon the patient and related co-morbidities. Understand that pelvic floor disorders rarely exist in isolation; therefore, you can have stress leakage, you can also have bladder dysfunction, voiding difficulty. So -- and you can have stress leakage and prolapse. You can have stress leakage, prolapse and voiding dysfunction. You can have all three of them with pre-existing

neurologic conditions, like Parkinson's, multiple sclerosis, diabetes.

So understanding that you've got operator variables and then you have patient variables as well, and then you have technique-related specifics. So they can be any combination, you know, of the above. Most of them, in my experience and in my extensive review of the literature, relate to the ones other than the material itself.

BY MR. SCHNIEDERS:

Q. And is it your opinion, Doctor, that with regard to the Ethicon products that you are testifying as an expert in this litigation, that those products do not cause mesh complications?

MR. SNELL: Form. Same objections as before.

THE WITNESS: There are complications related to Gynemesh and prolapse, such as erosion, that obviously it's the material that has eroded, but it is my opinion, as stated in my report, that this is not inherent in the material itself.

BY MR. SCHNIEDERS:

Q. Okay. And explain that for me.

A. Sure. I think I have explained it in my report quite extensively that, first of all, all patients who have prolapse have deficient tissue, nonfunctioning muscle and pre-existing issues that any of the surgical techniques that we employ in prolapse surgery come with inherent risks, and I think the literature is quite clear across thousands of studies involving tens of thousands of women that risks are related to surgery as a broad category and not specifically the Prolift or Gynemesh procedure. It's quite clear to me that it's very similar and sometimes lower than the baseline risk of surgery.

Q. So in those women, erosion would have occurred no matter what you put in them, right?

MR. SNELL: Objection, form.

THE WITNESS: With the understanding that most prolapse surgeries involve either suture or synthetic grafts or biological grafts or combinations thereof, complications such as wound complications, I'll take mesh erosion is simply one type of wound complication, the complications occur equally whether it's sutures or biologic grafts or synthetic grafts,

and I think the literature more than adequately supports that position.

BY MR. SCHNIEDERS:

Q. Doctor, when I say mesh complications, what does that mean?

MR. SNELL: Form, calls for speculation.

THE WITNESS: I don't know what you mean by that.

BY MR. SCHNIEDERS:

Q. What does it mean to you?

A. What does mesh complications mean to me? I guess literally it means any adverse event that may be associated with mesh.

Q. And what adverse events, in your mind, may be associated with mesh?

A. Again, counselor, maybe I didn't make myself clear, given that it is impossible to separate out the other variables, operator dependent variables, patient related risk factors, general techniques regarding prolapse surgery, the risks seem to be similar across the board and independent of the specific techniques.

Q. So when I asked you what mesh complication meant to you, you said it meant any

adverse event that may be associated with mesh, correct?

A. Yes, I'm just interpreting what you asked me.

Q. That's what you said, those were your words, right?

A. Those were my words.

Q. Okay. And when I ask you what adverse events might be associated with mesh, your answer is there are none?

A. That's not what I said, counselor. I gave you my answer.

(Document marked for identification as Toglia Deposition Exhibit No. 3.)

BY MR. SCHNIEDERS:

Q. I'm going to show you what I've marked as Exhibit 3, which is a copy of your website's front page. It's several pages long because if you go on the right side of the second page, you'll see there's a section entitled "Questions About Vaginal Mesh?"

Do you see that?

A. I do.

Q. Who wrote that?

A. I would say I was probably the author of

that.

Q. Okay. And at the very beginning there, it's got a link to the position statement from AUGS/SUFU, correct?

A. Correct.

Q. But what I want to go to is down the second to last page, and just so everybody is aware, and you know this, Doctor, everybody else in this room might not, but there's a section where you click for more, and that's where the rest of this language comes from.

Does that seem familiar with your website, Doctor?

A. Correct.

Q. So that's why it's several pages longer than the rest of it.

But if you go to the last page that has words on it, in the second to last paragraph it says, "Urogynecology Associates maintains a large patient database of women in whom we have performed these procedures, and we are continually reviewing our results. Our physicians have been involved in clinical research in this area, and, in general, our data suggests a largely positive experience and high patient

satisfaction."

Do you see that?

A. I do.

Q. This database, is that what you are discussing when you say that you review these things on a regular basis?

A. Yes.

Q. And did you think about putting your data into a form that you might be able to bring here today in order to support your opinions?

A. No.

Q. Why not?

MR. SNELL: I'm going to object. I don't think it's actually called for, but go ahead.

THE WITNESS: You know, I don't think that that would be something that would be -- it's not something I could easily put together, you know, quickly.

BY MR. SCHNIEDERS:

Q. But you are able to look at it and tell patients that are coming into your office that the data suggests a largely positive experience and high patient satisfaction?

A. That is correct.

Q. And going on to the last paragraph right here it says, finally, our physicians -- just so we're clear, Doctor, it's you and one other partner right now, correct?

A. That's correct.

Q. "Finally, our physicians have extensive experience in the evaluation and management of women who have experienced complications from transvaginal mesh procedures, including the surgical revision or removal of such devices."

Do you see that?

A. I do.

Q. When you say "complications from transvaginal mesh procedures," what do you mean when you write that?

A. I mean that if a women previously underwent a transvaginal mesh procedure or really any kind of surgery for pelvic organ prolapse or incontinence, whether it involved sutures or mesh material, that we have experience in evaluating and treating those conditions.

Q. So, as it sits here today with regard to the Ethicon products that you are opining about, the

products themselves don't cause the complications, it's some mixture of the patient, the doctor and potentially some other variable, correct?

MR. SNELL: Form.

THE WITNESS: It's a combination of all those things. I mean, if you do surgery without suture, you can't have suture-related problems. If you do surgery with suture, if it's permanent suture, you know, you can have mesh -- excuse me -- you can have suture related complications or adverse consequences, as I've previously published. And if you do procedures with biological grafts or synthetic mesh materials, there is a, you know, baseline risk as it is laid out in our report of, you know, percentages of patients that might experience exposure of the material.

BY MR. SCHNIEDERS:

Q. If a woman came in to your office and had previously had a Ethicon product, whether it be Gynemesh PS or Prolift or TVT and they had a complication, immediately you would understand that it wasn't that product that caused the complication, correct?

MR. SNELL: Objection, form, incomplete hypothetical, vague.

THE WITNESS: I'm not sure that I understand the foundation. If somebody had a Prolift procedure and comes to my office with exposed mesh, it's going to be my assumption that it is the Prolift mesh that is what I'm seeing in the vagina.

BY MR. SCHNIEDERS:

Q. But it would be your assumption that the Prolift mesh didn't cause the problem, correct?

MR. SNELL: Objection, same objection.

THE WITNESS: Wound complications are caused by problems with wound healing.

BY MR. SCHNIEDERS:

Q. Not the mesh, correct?

A. Not the mesh, correct.

Q. Okay. Would your opinion be the same if it was a Boston Scientific product?

A. Yes.

Q. So you don't believe that Boston Scientific products can cause complications, the mesh itself?

MR. SNELL: Form, overbroad.

THE WITNESS: I think complications can occur in people who have undergone implantation with these materials. I think that the opinion that I have expressed in my report is that these are known complications that occur with all of our surgeries to similar degrees.

BY MR. SCHNIEDERS:

Q. And I guess that's my question. You're saying that these are known complications that can occur with these products, but you're saying that across the board it's not the product causing the complication, correct?

A. It is not the product causing the complication, correct.

Q. It's something else, it's a variable of either the physician, the patient or some combination of those two?

MR. SNELL: Form.

THE WITNESS: It's always a combination of everything.

BY MR. SCHNIEDERS:

Q. But not including the mesh?

MR. SNELL: Same objection, form.

THE WITNESS: You can't have mesh

erosion if mesh isn't part of the procedure, so in that context, mesh erosion necessitates previous placement of mesh.

BY MR. SCHNIEDERS:

Q. And in that context, does the mesh cause the erosion?

MR. SNELL: Form, incomplete hypothetical.

THE WITNESS: I think the opinion that I state in my report that the material itself does not cause the complication.

BY MR. SCHNIEDERS:

Q. Is there any mesh that causes that sort of complication that's on the market or has been taken off the market in the last ten years?

MR. SNELL: Form, vague.

THE WITNESS: I think my opinion is limited to, you know, the products being -- what I prepared for and what I've written is specific to Prolift and Gynemesh PS. I'm happy to answer those questions as they relate to that.

BY MR. SCHNIEDERS:

Q. When you report an adverse event to the

FDA, you're able to give an opinion as to whether or not the product that you're reporting the adverse event on was the cause or was related, correct?

A. Correct.

Q. Okay. Every time you reported an Ethicon product to the FDA as an adverse event, you said it wasn't related, correct?

MR. SNELL: Objection, lacks foundation.

THE WITNESS: I don't recall ever saying that I was concerned that the material itself was the problem.

BY MR. SCHNIEDERS:

Q. What about when you reported an Apogee?

A. Again, it could be patient selection, it could be patient risk factors, we usually report all those. You know, this was a smoker, obese patient who had previous surgery, you know. I mean, obviously, I don't identify the surgeon individually, but I will make comment whether they came locally, you know, from a local institution, whether they came from another state.

Again, my role is not to pass any kind of judgment or make any kind of decision. I'm simply reporting what I'm finding, and I trust it to the FDA

that they're collecting similar information, if it does exist. So I'm simply reporting it in a non-judgmental manner. I'm not offering an opinion to them as far as what I think happened.

Q. Well, there's a subsection of the form that allows for you to say it's related or not related, correct?

MR. SNELL: Foundation.

THE WITNESS: I don't recall specifically. It's been a number of years since I've had to report something. I wouldn't argue with you if you told me specifically that there was an area that said it was related.

BY MR. SCHNIEDERS:

Q. It's been several years since you've reported anything as an adverse event?

A. Two years, I would say. I can't give you an independent recollection of the last time that I reported something of that matter.

Q. When was your last mesh revision surgery?

A. Maybe six months ago.

Q. You didn't report that as an adverse event?

A. So my understanding is that the FDA wants us to report on established products that were, you know, approved for the indication. So if somebody took a piece of Surgimesh or some Gortex mesh and had used it vaginally in the repair, and there was erosion of Gortex, which I think might have been the last one that I saw, I would not have reported that to the FDA.

But if someone had a manufactured product, like even things like NovaSure ablation or a device, you know, Therma -- whatever the Thermachoice device is or in this case Apogee Perigee, I report those type of cases.

Q. When is the last time you did a revision on a product like that?

A. Within the last year. I couldn't be more specific than that. There are not very common occurrences, fortunately, in our area.

(Document marked for identification as Toglia Deposition Exhibit No. 4.)

BY MR. SCHNIEDERS:

Q. So housekeeping wise, I think I marked as Exhibit 4 your box of your materials, and, as we said off the record, we're going to -- after the depositions tomorrow, you're going to put all your

materials in that box and leave that with the court reporter; is that fair, Doctor?

A. We will have copies -- I just want to make sure that I have copies for further.

MR. SNELL: He is talking about after the depositions.

MR. SCHNIEDERS: After tomorrow.

MR. SNELL: Yeah, that's fine. Just make sure it gets back to Dr. Toglia. In TVT last time he had an issue where --

THE WITNESS: I didn't get the material for four months. So, unfortunately, counselor, prior experience has got my guard up, and I mean no offense to you.

MR. SCHNIEDERS: That's fair, and, of course, you know that has nothing to do with us either.

THE WITNESS: I'm willing, but if I seem hesitant or reluctant, once bitten, twice shy, but I plan to be fully cooperative with whatever the Court requests of me.

BY MR. SCHNIEDERS:

Q. And then Exhibit 5 I've actually separately marked, this will not go in that box.

(Document marked for identification as Toglia Deposition Exhibit No. 5.)

BY MR. SCHNIEDERS:

Q. Exhibit 5 is your two invoices that you brought here today as well, okay?

A. Sure, yes.

(Document marked for identification as Toglia Deposition Exhibit No. 6.)

BY MR. SCHNIEDERS:

Q. Moving on to Exhibit 6, although I believe you have a copy of it over there, Doctor, your expert report.

A. Yes.

Q. Doctor, you are here today talking about your general expert report regarding Gynemesh PS and Prolift, correct?

A. That is correct.

Q. And this report, as we established earlier, was issued --

A. February 26, 2016.

Q. And that's your signature that appears on Page 25?

A. That is my signature.

Q. Does this report contain all of your

opinions you intend to offer in this matter?

A. It does.

Q. And, obviously, we've been doing it up to this point, but if you need that to refer or to answer any questions, clearly, go to it and use it.

A. I appreciate that.

Q. I have copies here, just to be -- make sure I've got everything, but I have copies here of the TVT expert report that was marked as part of the previous deposition.

I assume nothing about your opinions has changed since the time of your deposition?

A. That's correct. Nothing has changed.

Q. I will not mark that.

So I also have reliance list, which I think we established earlier in the deposition is actually the reliance list for your TVT report, and my confusion came from the fact that it has the same date at the very top there, and it didn't say TVT, so I think we have a copy of your reliance list for the Gynemesh and Prolift report somewhere around here, don't we?

A. Right. It's not in the exhibit that you marked.

MR. SNELL: You can give that to him and

mark that.

THE WITNESS: It's been in my report. I don't know what was provided to you, but my report is accurate.

MR. SNELL: You can give him that. That way he can mark it.

MR. SCHNIEDERS: I'm just going to mark that reliance list.

MR. SNELL: Sure.

MR. SCHNIEDERS: I'm marking Exhibit 7 as that reliance list.

(Document marked for identification as Toglia Deposition Exhibit No. 7.)

BY MR. SCHNIEDERS:

Q. Doctor, what we've now marked as Exhibit 7, I think we established earlier all the materials you brought today with you are somewhere on that list with the exception of one deposition that you've received I think since the TVT -- or I'm sorry -- since the actual report was issued; is that correct?

A. Yes, correct.

Q. And as we sit here today, you don't have any other materials to add to it or that you believe are missing, correct?

A. That is correct.

MR. SNELL: If I can say something, I just don't want there to be a misstatement on the record, and maybe I'm misremembering. I thought you had materials that Ostergard cited in his report too, or did you not have those?

THE WITNESS: I showed this to you earlier, counselor. This is the -- these are the materials that Dr. Ostergard cited in his report that I don't believe were previously marked. Earlier you asked me about the educational materials that I did not have them in my personal records, but I did know that they were somewhere here.

BY MR. SCHNIEDERS:

Q. And that binder is part of what I'm considering to be Exhibit 4 that's going to go in the box afterwards, fair?

A. That's fair.

MR. SNELL: That makes sense.

BY MR. SCHNIEDERS:

Q. And both the deposition and the materials from the Ostergard deposition and expert report are not a part of your reliance list, as it sits

today, but you have reviewed them?

A. Because they came after the fact.

Q. Okay. But aside from the materials from the Ostergard expert report and that deposition, everything is on the reliance list?

A. That's correct.

Q. Doctor, who drafted the reliance list for you?

A. The list itself was drafted by Mr. Snell's office with the understanding that much of the material were studies and reports that I provided to them.

Q. Were there any materials that they provided to you that you did not ask for?

A. My recollection is that there were studies that I was familiar with that I may not have had a hard copy of, and I received a hard copy from them, but, in general, you know, you're looking at how I spend many of my nights and weekends over the past 25 years, the type of materials that I read. So much of this is stuff that I've been familiar with for decades or from whenever it was published.

Q. So as I'm looking at your invoices, the last one was billed on February 29th of 2016, which was

right about the same time, if not the same day --

A. Correct.

Q. -- that you issued your report.

So does that invoice encompass all the time that you spent up to the time you issued your report?

A. With regard to the general Prolift, Gynemesh report and the case specific reports, yes, separate from the TVT.

Q. Okay. So are these invoices that I'm looking at that we've marked as Exhibit 5, do they not include your work on TVT?

A. That's correct.

Q. Okay. There are separate invoices for that?

A. That's correct.

Q. And so you're keeping track of your time, whether you believe you're working on the Prolift side of things or the TVT side of things?

A. Separately, correct.

Q. I think that here as of January 31st of this year, you had 12 hours billed at $400 an hour, and that was to the Ethicon Gynecare mesh litigation MDL, and it says 200, although, obviously, that's not the right MDL.

Does that look correct.

A. Is it 2000? What's the --

Q. Well, either way, but that's as of January 31st, that's the date that --

A. Yes. The inclusive dates are on the list and you can see -- I mean, I know you weren't at the TVT deposition, but we switched -- I switched gears after that, correct. So I believe it's a total of about 47 hours that was billed by the end of February, if I'm not mistaken.

Q. It's 35 on this one and then it was 12 on this one, so 47 hours as of the time that you issued your report that you had spent working specific to these two products we're here today for?

A. Mm-hmm.

Q. Is that a yes?

A. Excuse me, that I've billed for.

Q. That you've billed for?

A. Correct.

Q. Okay. As we sit here, do you still have uninvoiced time?

A. I do.

Q. How much time would you estimate that you have that has not been billed?

A. I want to say maybe an additional 20 hours.

Q. And that goes to what my question was, and maybe I wasn't very clear, so I apologize. You issued your second invoice as of February 29th of 2016.

Did that include -- because it says consultation fee, 2/1/16 through 2/29/16, did that include all the work that you had put in up until you signed your expert report?

A. The question that you had asked me previously is what I billed them, and I've given you the information that I billed them. That would include all the work that I did up until the final date on that bill. Anything outstanding is subsequent to that date. Is that what you're asking.

Q. Yeah. So this February 29, 2016 --

A. There's no additional unbilled time for that time.

Q. Okay. I apologize for being scattered on it. To make it clear --

A. No, you were quite clear. You asked me what time I had billed and I answered what time I had billed. So I was clear on what you asked me, counselor.

Q. So then as of March, so from the date that you signed your expert report forward, you've done an additional 20 hours approximately?

A. Approximately.

Q. Did that include deposition preparation time with Mr. Snell?

A. It will.

Q. Did you prepare for today's deposition?

A. Yes.

Q. How long did you spend with Mr. Snell or any of his partners to prepare?

A. Ninety minutes.

Q. So then the other 18 and a half hours or so would have been spent reading literature?

A. No. Again, not wanting to waste the Court's time, I wanted to read through the report and make some tabular notes, so when you asked me a specific question, I'd be able to find that information quickly, so reading, rereading, rechecking, summary type statistics. As I was provided, for example, Dr. Ostergard's deposition and materials, reviewing.

Q. I think you testified to this, but just so we're clear, when you met with Mr. Snell and anyone else from his office to prepare, they didn't show you

any documents?

A. I'm not clear.

Q. Did they show you any documents when you were preparing for your deposition?

A. They provided me with Ostergard's.

Q. But that's it?

A. That's the example, yes.

Q. Anything else?

A. Specifically, no, not that I can think of.

Q. Have you ever seen any internal Ethicon documents?

A. I have seen Ethicon documents. I believe that was covered in the last TVT report. I do not think I've seen anything additionally since.

Q. The last TVT deposition?

A. Excuse me, the TVT deposition, correct.

Q. So has the defendant ever shown you any internal documents?

A. The ones that I just mentioned. There were documents provided -- there were documents of internal communication provided to me by Mr. Snell initially that were reviewed relevant to the TVT report. I mean, obviously, some of the information is

relevant to the content today, but I've received no additional documents other than the ones that we listed for that report, and I believe they're listed on our reference list here as well.

Q. Anything that you're talking about that you had seen, you would have -- you believed it was on your reliance list for the TVT report?

A. I do believe, yes.

Q. Doctor, earlier you mentioned a product called the Sphinx.

Do you recall that?

A. I do.

Q. What was the Sphinx? Is it Sphinx or the Sphinx?

A. I think the project was just generically called Sphinx, as a pun on the word sphincter, and I believe we covered that during the TVT deposition.

Q. What is the Sphinx?

A. The Sphinx is a large stone structure in Cairo, Egypt. Sphinx was a project that looked at -- Sphinx was a project that looked at whether or not we could extrapolate the integral theory to the posterior compartments specifically for fecal continence. It's my belief, as it is the belief of others, that the body

doesn't go out of its way to come up with new mechanisms to control a common function. So if the body already has a functioning mechanism for the control of urinary -- of urine, that's similar type physiologic mechanisms might exist for fecal control. So we were exploring the feasibility of that, and that has also been explored by other surgeons with other companies.

Q. Doctor, would you say that, in your experience, Prolift and TVT have clearly shown that erosion occurs at the incision line all the time?

MR. SNELL: Form.

THE WITNESS: Can you repeat the question.

BY MR. SCHNIEDERS:

Q. Sure. Would you say that, in your experience, that Prolift and TVT clearly show that erosion occurs at the incision line all of the time?

MR. SNELL: Objection.

THE WITNESS: As a general rule, the exposure that I have seen and that I have read about tend to be in the incision line. Less commonly, you might see an erosion at other points of tension. Obviously, there are

probably situations where the vaginal epithelium was unintentionally breached, and so then you would have exposure of mesh that was subsequently discovered that likely was there initially.

BY MR. SCHNIEDERS:

Q. If there's more surface area of a sling that is directly below an incision, is there a higher risk of erosion?

A. More surface area than what?

Q. Than less surface area.

MR. SNELL: Form.

THE WITNESS: I'm not sure that I understand what you're asking me.

BY MR. SCHNIEDERS:

Q. Is it better to eliminate as much surface area of sling directly below an incision in order to keep a lower rate of erosion?

A. I don't believe so.

Q. Does a larger surface area of sling directly below an incision increase the risk of erosion?

A. Not that I'm aware of.

(Document marked for identification as

Toglia Deposition Exhibit No. 8.)

BY MR. SCHNIEDERS:

Q. Let me show you what I've marked as Exhibit 8. This is an e-mail string from inside of Ethicon. At the very top you see that there's an e-mail from a gentleman named Gene Kammerer?

A. I do.

Q. Do you know Gene Kammerer?

A. I do.

Q. Who is Gene Kammerer?

A. Gene Kammerer I believe was an engineer consultant that worked with the R&D team at Ethicon on some of their projects. He's one of the project people that I worked with directly, probably was my most direct contact regarding the Sphinx or PASS procedure as we were considering it.

Q. And you see the subject he's responding to there says re: Dr. Toglia's comments on Sphinx and PASS.

Do you see that?

A. Yes.

Q. Okay. And we don't need to go through that e-mail. You're welcome to look at it, if you like, but the very first e-mail is at the very bottom,

and that's also from Mr. Kammerer, and on the second page it continues, "As you know I have been keeping a dialogue going with some of the advisory panel surgeons regarding our work and the concepts. Dr. Toglia has responded to the changes we made to the PASS concept and feels adamant that the 2 lateral incisions are crucial to its success. He has also provided some insight to the customer database which I haven't heard in our market research interviews. Here are some of his comments," and then you see what at least Mr. Kammerer is saying is a comment from you.

Do you see that?

A. Yes.

Q. Okay. Why don't you read that first paragraph right there regarding the two?

A. Regarding the 2 incisions versus a midline incision, as you know, there are many reasons why I feel that a single midline incision is a bad idea. Mostly, I am concerned about the erosion of the sling material through the perianal skin. Our experience with Prolift and TVT clearly show that erosions occur at the incision line all of the time, which is I think what I just stated to you. The perianal skin is very thin, and the sphincter is

located very close to the skin. Therefore, a post anal sling will sit very close to the surface epithelium as well, and a crescent incision will significantly increase the surface area of sling directly beneath the incision and, therefore, the risk for erosion. A significant erosion rate will be the death of this procedure.

Q. This procedure, as we stated earlier, never made it to market; it was abandoned before it got there, correct?

A. I would like to think that it was placed on a shelf. Abandoned is kind of a cruel word for the parent of the concept.

Q. Well, at any rate, it's not on the market currently?

A. No. There are no sling based repairs on the market for this problem.

Q. Okay. And were you being truthful when you told Mr. Kammerer that the surface area of sling that is directly beneath the incision would increase the rate of erosion?

MR. SNELL: Objection, lacks foundation, assumes --

THE WITNESS: I mean, this was my

theory, and I'm sorry, I mean, what you asked me earlier was -- I didn't hear you say below the incision. I simply heard you say below the epithelium. My point was at least in this location, you know, this is not the same location, by any means, compared to, say, the suburethral or the vagina but in basically the post anal area, it was at least my theory that we would be better off with separate lateral incisions as opposed to a contiguous incision.

BY MR. SCHNIEDERS:

Q. Would you agree with this statement that a significant erosion rate would be the death of the procedure?

MR. SNELL: Form, lacks foundation.

THE WITNESS: No. I think that with regard to this particular concept, which was the PASS procedure, that I was concerned that that would be a significant limitation. Obviously, I had no data because there was no data to support that, but I was -- I don't think you can extrapolate what I'm saying here to anything other than the concept of what we have here.

BY MR. SCHNIEDERS:

Q. What kind of mesh was used in the Sphinx?

A. Well, to be determined. We tried a variety of materials. I can't tell you that we ever got to that, you know, to the specific platform.

Q. Isn't it true that you started off with the concept of the TVT mesh?

A. Well, we had to play around with something, and what was readily available to Ethicon and Ethicon engineers were the TVT material, and so we did utilize TVT passers and the TVT mesh to see if we could anatomically place that material within that space.

Q. And that's the mesh you were using when you were concerned here in 2009 regarding erosions, correct?

A. One had nothing to do with the other. It had to do more with the type of incision being made, which is different than the type of -- we don't make lateral incisions next to the urethra.

Q. So you wanted to make a different type of incision, correct?

A. Given that we were operating close to

the rectum where stool comes out of, you know, if I had -- you know, my concept was how can I locate the incisions a little bit away, away from the actual anal verge so that it's not in direct contact with the passage of stool. Additionally, considering the normal surface tension when a person sits down that would be placed on the perianal area, that's much more susceptible to say midline tension, we were looking at incisions that were non-midline, but, again, I don't think that this -- I don't think that I'm necessarily commenting on my concerns relative to the other procedures, but I was trying to use terms that they were familiar with based upon their other products.

Q. Like erosion?

A. I'm sorry.

Q. Terms they were familiar with on their other products like erosion?

A. No. I'm sorry, as far as the location of the incision. They were used to -- all of their sling products were done through a midline, vertical incision, and I was suggesting in this concept that the incisions be at a right angle to that, obviously in a different location, and I was trying to position -- I was trying to position the incisions away from the anal

verge. And rather than one contiguous incision, I was suggesting two smaller incisions.

Q. Fair to say that you were attempting to decrease the surface area of sling that was directly beneath the incision, correct?

MR. SNELL: Form.

THE WITNESS: There were many different things that I was thinking about doing. And, again, that's a very different area, the concerns are somewhat different. The tension lines are different. We now have the added possibility of stool, you know, close to the incision. I was simply trying to move the incisions away from the anal verge, as I've already stated.

BY MR. SCHNIEDERS:

Q. And that's because your experience with Prolift and TVT clearly shows that the erosion occurs at the incision site all the time?

A. No. It was for the reasons that I just mentioned. In my head, I was thinking I want to get these incisions away from the anal verge, away from the path of stool. I think that there's different surface tension forces next to the anus, and so I at least

wanted to start with the concept would it be feasible to place the incisions there.

And they would say, well, why, why do you think that? And I would, again, try to communicate to them in their own language, and I would say, well, as you know, we were aware of circumstances where the slings are showing exposure, and, you know, the one factor at the time that was being considered was the location or type of incision.

The French, when they did their TVM products, also were looking at transverse incisions as opposed to midline incisions.

Q. Doctor, yes, no or you can't answer, larger surface area of sling directly beneath an incision increases the risk of erosion?

MR. SNELL: Objection, asked and answered. You don't have to answer it yes, no or I don't know. You told him before.

THE WITNESS: I've already stated my answer, counselor. I'm really trying not to be difficult. I honestly -- and I realize that you have no expertise in this area of the body, but there were unique challenges working near the rectum, and I was trying to address those,

you know, again, just based on theory. There's no evidence that what I said would have borne out to be true. It may have turned out that a midline incision was perfectly feasible and/or easier. I was just starting with a slightly different concept for the reasons that I explained.

In addition, there was another product in development for a similar indication, and I was trying to make this one different, you know, in its approach.

BY MR. SCHNIEDERS:

Q. So the reason you said the Sphinx at that time was because you were trying to differentiate the product and because you had a theory that potentially the surface area of the sling above the incision site could increase the risk of erosion, correct?

MR. SNELL: Objection, misstates.

THE WITNESS: One of a number -- again, I was trying to explore a unique concept that whether or not this would work to our advantage. You know, obviously we already had experience with midline incisions. In general,

they worked well. I was trying to come up with a more unique concept. You know, with two separate incisions, I was hoping that there would be no tension at the midpoint or directly beneath the incision line.

BY MR. SCHNIEDERS:

Q. But you weren't concerned about the amount of surface area of the sling beneath the incision, correct?

A. I would say yes. I would say surface area was really not my concern but, again --

Q. That's what you wrote down here?

A. I understand.

MR. SNELL: Actually, no, you're misstating. That is not his writing, so don't say he wrote that.

THE WITNESS: That's true, good point.

MR. SNELL: That lacks foundation.

BY MR. SCHNIEDERS:

Q. Are you saying that you didn't have a conversation about this topic with Gene Kammerer?

A. No, no. I'm saying I had a conversation. I'm just saying I did not write these paragraphs, that these are not my words, okay. But,

again, I was trying to explain to them in terms that an engineer, who is familiar with the different product, would understand. But, obviously, I did not edit -- write or edit this information.

Q. Did you ever e-mail with Mr. Kammerer?

A. Yes.

Q. Are you able to testify this wasn't an e-mail that he had cut and pasted into this e-mail that he sent?

A. I have no idea, sir.

Q. And did you go to look in your own personal e-mails to see if you could find this one from 2009?

A. I no longer own -- I no longer have -- that computer has been destroyed along with all of its material. I don't own the rights to this concept, so I was informed to discard all of that once the product was abandoned, as you so put it.

Q. And you went through and cleaned out all of your e-mails and deleted all of them at that point?

A. I deleted all of those e-mails and then when I wiped the hard drive on that computer, that just went wherever those bits go, yes.

Q. Sure, sure. But there's a server

somewhere where those e-mails probably exist; you know that?

A. I don't know. I don't know. I honestly don't know.

Q. What account would you have been using at that time to communicate with Mr. Kammerer?

A. I honestly don't know.

(Document marked for identification as Toglia Deposition Exhibit No. 9.)

BY MR. SCHNIEDERS:

Q. Let me mark as Exhibit 9 another e-mail from Mr. Kammerer.

Is it possible that this e-mail address that you sent him an e-mail from, that's a Verizon address, is that the one you might have been using?

A. It would seem to me that this would be the account that I e-mailed him from, correct.

Q. Do you currently have the Verizon.net e-mail address?

A. Yeah, and I would appreciate for privacy reasons if we didn't go into any more detail than that, given that this is a public document.

Q. I'm assuming he's going to ask to have most of this sealed, to be honest.

MR. SNELL: We'll go ahead and seal anything personal.

THE WITNESS: I apologize, but there are concerns about identity theft and information that I have.

BY MR. SCHNIEDERS:

Q. I'm not going to e-mail you, I promise.

A. Yes. So, again, this represents sort of my emotional response perhaps, and, again, remember as the parent to the concept, I was a little bit resistant to people wanting to change my concept because I thought that I had thought them out pretty clearly.

Q. So, Dr. Toglia, if you go to the e-mail down below where you're actually e-mailing to Mr. Kammerer, and the subject is re: checking in, because I think if you go back there was originally an e-mail from you asking if the project was dormant?

A. Sure.

Q. But if you see here the third, and this is I think what you're talking about your emotional response to the way that they were approaching the project perhaps, but that third line starting "Ethicon," could you read that sentence or that paragraph there?

A. I'm happy to. Let me just make sure I understand you clearly. You want me to begin reading the paragraph entitled "another key concept."

Q. No. The one that starts with "Ethicon has enjoyed."

A. Oh. Ethicon has enjoyed its greatest success with simple, straightforward thin sling - the TVT. Attempts to develop more comprehensive mesh solutions have far -- have not only been far less successful, but as a class have had serious complications and are rapidly falling out of favor.

Q. What mesh solutions, comprehensive mesh solutions were you talking about there?

A. I honestly don't know. This is from six years ago. These may have been other concept projects that -- at one point I sat down with them and we went over eight to ten new concepts for other projects within this sphere. Obviously, I would think in my mind if it was an existing project, I would have used the existing product's name.

Q. How many comprehensive mesh solutions can you think of that have had serious complications?

A. As a class, I don't know of any actually at this point.

Q. Well, then what did you mean?

A. I might have been referring specifically to the IVS Tunneller. You know, the IVS Tunneller, this was a concept that also involved the tunneling of mesh through several compartments over a long period of time, and the IVS Tunneller was also in its initial form both anterior and posteriorly involved similar type concepts. So now that I sort of reinvigorate my brain, I wouldn't be surprised if I'm referring to the IVS Tunneller in this statement.

Q. You're referring to the IVS Tunneller with regard to Ethicon because it says Ethicon products right there?

A. I didn't say that Ethicon's attempts, I just said attempts. The bottom line is that I don't recall, as I sit here, specifically what I was referring to in this e-mail. I'm sorry.

Q. So it could be that you're talking about things like Gynemesh PS, correct?

MR. SNELL: Objection, lacks foundation.

THE WITNESS: I highly doubt this had anything to do with the Gynemesh PS.

BY MR. SCHNIEDERS:

Q. Could have been Prolift, right?

MR. SNELL: Same objection.

THE WITNESS: I honestly don't think it had to do with Prolift, in all honesty.

BY MR. SCHNIEDERS:

Q. Explain for the jury what the Tunneller does.

A. Explain to you?

Q. To the jury, you're talking to the jury right now.

A. Am I talking to the jury right now? Is that who I'm talking to?

MR. SNELL: You can just answer his questions to the best of your ability. Sometimes lawyers say things --

THE WITNESS: I'm sorry. Got you. I mean, I'm just very literal, and I just want to make sure I don't misstate anything. Well, I mean, obviously, to deliver a product to its destination and whether it's laparoscopy or cannulas for TVT, cannulas for Prolift, you have to have a way to deliver the product to its final destination, and, again, the PASS concept involved placing a mesh sling below the anal sphincter and towing it up, if I remember

correctly, through the obturator space as a point of exit.

BY MR. SCHNIEDERS:

Q. And what were the serious complications that were related to that?

A. There weren't anything. The PASS concept never was done in a live person.

Q. So, sitting here today, you can't think of any comprehensive mesh solutions that were developed as a class that have had serious complications and are rapidly falling out of favor that you might have been referencing in January of 2010?

MR. SNELL: Objection, asked and answered.

THE WITNESS: Yes, I mean, again, I cannot tell you what I specifically had in mind behind that statement. I was clearly, as you can see from the overall emotional tone of the letter, of the e-mail that I was being very emotionally resistant to the idea that we change anything. We hadn't even done anything with it yet. I wanted to test the original idea, as I had laid it forth to see what the feasibility was, and I was not open at the time

to making changes.

BY MR. SCHNIEDERS:

Q. But sitting here today, you're sure that it's not Prolift that you were talking about?

A. I don't recall it as being Prolift at the time, no.

Q. And you're sure it's not Gynemesh PS that you're talking about?

A. You know, I think I would have listed it by name. I listed their success by name. I think if I had a specific concern, I would have listed that as well.

Q. You didn't mention Tunneller there, did you?

A. No. I was talking about just the overall where we were conceptually, you know, at the time.

MR. SCHNIEDERS: Maybe now is a good time to take a break.

(Brief recess taken at 3:27 p.m.)

(Deposition resumes at 3:38 p.m.)

MR. SCHNIEDERS: We're back after a short break.

MR. SNELL: Let's mark that last portion

confidential. Let's mark the whole thing. For the purpose of whoever is going to be reviewing this on this issue, there are discussions about intellectual property concepts, thoughts by the doctor and what not which he has concerns about it falling into other people's hands. That is the basis and the purpose.

THE WITNESS: Thank you.

BY MR. SCHNIEDERS:

Q. Doctor, are you doing any current research on polypropylene meshes?

A. I mean, I consider the reviews that I do here where, you know, basically systematic review is a type of, you know, research project. In terms of -- I'm not currently engaged in any clinical trials of that material.

Q. Are you engaged in any attempts to publish any retrospective data or anything like that?

A. My current role in that arena is that, you know, since I serve as an editor of two journals, my energy is spent actually reviewing studies and manuscripts submitted for publications, much of which is on the subject matter that we're discussing today, but I have no -- I have nothing pending to be

published.

Q. Have you ever written anything on the Burch procedure?

MR. SNELL: Form.

THE WITNESS: There may be mention in a book chapter, but I have not published on my personal experience with that procedure independent from a more general discussion.

BY MR. SCHNIEDERS:

Q. Have you ever written anything on biologic tissue slings?

A. I have not.

Q. You would agree that you're not an academic physician, correct?

MR. SNELL: Form.

THE WITNESS: I would not agree with that, no.

BY MR. SCHNIEDERS:

Q. Explain, please.

A. Much of the work that I do is equivalent to what you do in academics. I was previously employed at an academic institution. I'm simply not employed by an academic institution. Obviously, I have appointments at an academic institution. Our current

institution involves -- does have a residency, so I am directly involved in teaching and the creation of academic curriculum, resident education, resident teaching. I do speak nationally in postgraduate medical educations through venues such as AUGS, Society of Gynecologic Surgeons. Those are academic endeavors.

Q. But you also have a private clinical practice, correct?

A. Correct.

Q. So insofar as you are a private clinical physician, in that portion of your life, that would not be academic medicine, correct?

MR. SNELL: Objection.

THE WITNESS: I disagree. Again, before I came here today, I was in the operating room in my private practice. I had a resident with me and a medical student with me. That is academic in nature. We are discussing and teaching. So it's all of the above.

BY MR. SCHNIEDERS:

Q. I may have asked this before, so forgive me if I have. Are you currently under contract as a consultant for any pharmaceutical or device company?

A. You did not ask that before. I

currently consult with a pharmaceutical company. I had a consulting -- an active consultant agreement with a medical device company that if we wait another week will no longer exist.

Q. So would that be AMS?

A. That would be, very good.

Q. And who is the pharmaceutical company you consult with currently?

A. So it would be Astellas Pharma whom I've consult with since 1994, I believe, unrelated to what we're discussing today.

Q. And would that be the longest standing relationship you have in consulting with a pharmaceutical or a device company?

A. I believe so.

Q. Have you continuously worked for Astellas since 1994?

A. I have never worked for Astellas.

Q. Point taken. Have you continuously worked with Astellas since 1994?

A. You know, intermittent relationship. There are periods of time, different cycles of the economy where they are more interested, less interested. It varies widely. I would say, as a

general rule, my involvement in the past several years has been fairly minimal.

Q. You would agree that less rigidity with regard to mesh is better, correct?

MR. SNELL: Form, overbroad, lacks foundation.

THE WITNESS: I would not agree.

BY MR. SCHNIEDERS:

Q. Okay. Explain to me why not.

A. I'm not sure what the foundation is that you're asking me. Less better for what?

Q. Less likely to cause or impair -- strike that.

Less likely to impair sexual function?

MR. SNELL: Same objection, incomplete hypothetical.

THE WITNESS: Yeah, it's more complicated than that, counselor. Please keep in mind that we don't have any cutoffs or agreements, there are no expert consensus as far as what's lightweight, what's not lightweight, what's rigid, what's less rigid, you know. These are just sort of a continuum of ideas. You know, everything is relative.

You know, is this lightweight, well, it might be lighter than something previously, not as light as something later. But, in general, my objection is that we don't have cutoffs, no one has ever published, you know, this is heavy, this is light. There's no expert consensus. People do throw around the terms relatively, this is lighter weight mesh, this is lightweight, but I don't know what the cutoffs are, and the same would apply to rigidity.

Q. So there are cutoffs, you just don't know what they are?

MR. SNELL: Objection.

THE WITNESS: If I don't know -- if I don't know what they are, how would I know that there were cutoffs?

BY MR. SCHNIEDERS:

Q. You said but I don't know what the cutoffs are, and the same would apply to rigidity. That implies that there are cutoffs somewhere, right?

MR. SNELL: I'm going to object.

THE WITNESS: No.

MR. SNELL: Hold on. You have to let me object. You're actually misstating his

testimony. His testimony he did say there is no cutoff.

MR. SCHNIEDERS: I'm again going to read because I don't need you to speak for the witness.

MR. SNELL: I'm not speaking, but you are misstating his testimony --

MR. SCHNIEDERS: I'm reading from it right here.

MR. SNELL: His answer was 21 lines long.

MR. SCHNIEDERS: He said I don't know what the cutoffs are and the same would apply to rigidity.

MR. SNELL: No, his answer was 20 lines longer than the little thing you pulled out of there.

MR. SCHNIEDERS: Whatever.

BY MR. SCHNIEDERS:

Q. Are there cutoffs?

A. There are currently no established cutoffs, there are no definitions, and there is no expert consensus.

Q. But, theoretically, there are cutoffs

somewhere, right?

MR. SNELL: Form, hypothetical.

THE WITNESS: No.

BY MR. SCHNIEDERS:

Q. No?

A. There are no established, universally accepted definitions, cutoffs, consensus of opinion.

Q. Doctor, listen to my question. I said theoretically, there are cutoffs. I didn't say they were established, universally accepted cutoffs. I said theoretically there would be cutoffs, right?

MR. SNELL: Objection, vague, calls for speculation.

THE WITNESS: I don't know how further to answer that. I'm sorry.

BY MR. SCHNIEDERS:

Q. Why hasn't AUGS filed a consensus statement on what levels of rigidity are acceptable?

A. I can't answer that question. I can't speak for AUGS.

Q. Are you a member of that society?

A. Yes.

Q. Have you ever gone to them and said why don't we put out a consensus statement on this?

A. No, I have not.
Q. Did you go to them and have any input in their position statement regarding vaginal mesh?
A. I did not have any direct input into that statement.
Q. Did you ever review a draft of that statement?
A. I don't believe that I reviewed a draft of that statement.
Q. Were you ever circulated a draft of that statement?
A. I might have been circulated a draft of that statement. I don't independently recall that.
Q. And not to -- honestly not to make you uncomfortable, but had you received a draft of that statement, would that have been to that Verizon e-mail address?
MR. SNELL: Objection.
THE WITNESS: I don't know. I don't know. That would be one of the more common addresses that I might receive material, but I didn't receive it.
BY MR. SCHNIEDERS:
Q. You didn't receive it, or you don't know

if you received it?

A. I think it's the same thing. I do not recall that I have ever received a draft, to the best of my knowledge, of that statement, of the proposed statement.

Q. Sorry didn't mean to interrupt.

Do you know who the authors are of that statement?

A. I do.

Q. Do you know them personally?

A. I do.

Q. Do you consider yourself to be friends with those gentlemen?

A. They are colleagues of mine.

Q. Are they people you would see socially as well or just professionally?

A. I think those lines are blurred in my area, as I'm sure they are in yours. You know, we have social events at our academic meetings, our scientific meetings. I don't believe I was in any of their wedding parties or went on vacation or sat in a Jacuzzi with any of them, but I would say, certainly, you know, I think it would be accurate to say that we have collegial relationships that are both social and

academic.

Q. Have you ever discussed authoring anything with any of them?

A. I would have to look at the comprehensive list of the people on that if you want to share that with me.

Q. We can cover that in a moment.

A. Yeah.

Q. You are not an expert in chemical engineering, correct?

MR. SNELL: Form. This is covered in the earlier deposition.

MR. SCHNIEDERS: And I am aware and that's why I'm asking it.

BY MR. SCHNIEDERS:

Q. Do you hold yourself out as an expert in chemical engineering?

A. I think -- no, I don't hold myself out in a general sense in chemical engineering. I think I have expertise in this particular arena in front of any audience that I might be asked to participate as it relates to polypropylene mesh being used for its intended purpose.

Q. You're not an expert in pathology,

correct?

MR. SNELL: Objection.

THE WITNESS: I'm -- I don't have any certification in pathology. I have certainly an in-depth knowledge and, again, you know, if we were to go to the Villanova game together, I'd probably know more than the majority of people at that game.

BY MR. SCHNIEDERS:

Q. But you would defer to a pathologist, correct?

A. I don't know what you mean by "defer." I mean, if we had a disagreement, I wouldn't stand up and say you're a pathologist, you're absolutely right. No, I wouldn't defer in that regard.

Q. So you believe that you have an equal expertise as a pathologist?

A. I don't know where you're getting this from. I never made that statement.

Q. You would agree that a pathologist has a greater expertise in pathology than you do?

MR. SNELL: Form.

THE WITNESS: Yes, I would say, in a general sense, a pathologist has a more

in-depth level of knowledge than I.

BY MR. SCHNIEDERS:

Q. You agree you're not an expert in polymer chemistry, correct?

MR. SNELL: Objection, asked and answered in earlier deposition.

THE WITNESS: I think relative to the topic at hand, I would be considered by many to possess expertise in polymer chemistry.

BY MR. SCHNIEDERS:

Q. Relative to a jury, but not relative to a polymer chemist, correct?

MR. SNELL: Same objections.

THE WITNESS: You know, in terms of the application of this material within the human body, I've got a pretty good understanding of the working of polymer, yes. I have a degree in biochemistry. I've been reviewing this material extensively. I am certainly reading materials that are beyond what the average gynecologist or even urogynecologist female pelvic medicine or urologist would have reviewed.

BY MR. SCHNIEDERS:

Q. When was that degree in biochemistry?
A. 1985.
Q. And when is the last class you took in biochemistry?
A. Well, I mean, I'm constantly reading material. Obviously at this stage of the game I don't pay to enroll in college courses, but my -- you know, foundation of my knowledge did not end when I graduated from college.
Q. When is the last class you took in biochemistry?
A. I took a class in medical school in biochemistry.
Q. About what year would that have been?
A. That would have been 1986, '87.
Q. You've never done bench research on polypropylene, correct?
A. I have not.
Q. You've never done lab research on polypropylene, correct?
A. I have not.
Q. You've never done any sort of pathological analysis on explanted polypropylene, have you?

MR. SNELL: Form.

THE WITNESS: I have not. Understand that I've done lab work as it pertains to my consultation with polypropylene products in medical, you know -- in the medical arena.

BY MR. SCHNIEDERS:

Q. When you explant mesh, what do you do with that mesh?

A. The majority, depending upon -- you know, depending upon the situation, the majority of that material is sent to pathology for identification and labeling.

Q. Okay. You don't do that yourself, you send it to a pathologist?

A. Well, I'm operating on a patient, so I can't do both things, so I will send that to the pathologist.

Q. Could you?

A. Could I what?

Q. Could you do what the pathologist does?

A. Given that what the pathologist does is typically measure the dimensions of the material and simply reports that I have in front of me a 2 by 1 centimeter piece of blue mesh, that I can do, correct.

I can't tell you that in the medical world that there's any further analysis being done routinely.

Q. You've never published any opinion that polypropylene does not cause a foreign body reaction, correct?

A. Well, that's a double negative so -- and I do want to answer you accurately, so if you can restate that question without a double negative, I would appreciate it.

Q. Have you ever published an opinion that polypropylene does not cause a foreign body reaction?

A. Of course, polypropylene causes a foreign body reaction. Any foreign material implanted in the body will cause a foreign body reaction. That's what foreign body reaction is by definition.

Q. You are not an expert on warnings, correct?

MR. SNELL: Objection.

THE WITNESS: I don't hold myself out to offer an expert opinion on warnings, although I have, you know, ample experience in, you know, reading about them and reading those materials.

BY MR. SCHNIEDERS:

Q. You're not a biomechanical engineer,

correct?

A. I am not, no.

Q. I think we're going to get sideways here. You are not an expert on the design of medical devices, correct?

MR. SNELL: Objection, covered in his first deposition extensively.

THE WITNESS: I have worked on the design of medical devices. I have worked on the design and redesign of existing devices, as well as the device -- the medical device that we referred to earlier as the PASS device.

BY MR. SCHNIEDERS:

Q. And have you ever designed a device that made it to market?

A. I have not.

Q. I don't say that to cruel.

A. No, I apologize. I had -- and, again, I'm a relatively humble person. I had extensive input into the design of the TVT Exact, which is currently on the market.

Q. You had extensive input into the design before it went to market?

A. Correct.

Q. Do you know what standards a manufacturer must follow in designing mesh products?

A. I have a general awareness, a general awareness only.

Q. But you couldn't cite us CFRs or statutes or anything like that, correct?

A. I couldn't cite it, no.

Q. Have you ever seen the statutes that relate to the responsibilities a manufacturer holds in designing a product?

A. I don't recall, no.

Q. Have you ever reviewed any of Ethicon's standard operating procedures relating to design?

A. I do not believe so.

Q. Do you know what a clinical expert report is?

A. I believe this is the second one that I've issued in this arena, if I'm not mistaken. Is this what we're referring to?

Q. What you've issued is a clinical expert report, that's your definition of it?

A. Yes.

Q. Do you know what a design history file is?

A. In a general sense.

Q. What is it?

A. You know, when a manufacturer sets out to design a product, they would keep track of the history of that development and they would keep track of the communications between the different parties and the steps along that -- along that design.

Q. All right, Doctor. So earlier we were talking about two days that you put in the Gynemesh PS on your operating days.

What days are your operating days currently?

A. How is this relevant to the testimony that I'm giving? I operate two days a week. Is that not sufficient information?

Q. If you really don't want me to know what day, it's fine.

A. Yes, thank you.

Q. Two days a week?

A. Correct.

Q. And that's every week?

A. Correct.

Q. And how many surgeries do you do on those two days, typically?

A. Sure, I previously answered that on

average, I'll do between six and eight procedures, and they are virtually all related to pelvic floor disorders.

Q. Are there any surgeries that you're doing currently that are not related to pelvic floor disorders?

A. There may be some surgeries that are more general gynecology in nature. For example, if a woman is sent to me with prolapse and she tells me she has bleeding, I may first have to do a D&C or a biopsy or some other general thing prior to completing the treatment for the prolapse. So I would say it's within the sphere of gynecologic surgery and urogynecologic surgery.

Q. So vast majority of your procedures currently are going to be a TVT product or the Gynemesh PS, correct?

A. No. The vast majority of my procedures are prolapse and incontinence. Procedures, the prolapse procedures could be native tissue plication, obliterative procedures, Gynemesh or sacrocolpopexy procedures. The majority of my incontinence procedures are retropubic TVT procedures, specifically TVT Exact.

Q. So out of approximately 12 surgeries

that you perform weekly, how many of those surgeries are likely to be Gynemesh PS?

A. I didn't say I did 12 surgeries a week, for clarification. I said I did between six and eight procedures a week.

Q. Oh, I thought that was per day.

A. No, I'm sorry.

Q. Okay. Six to eight per week?

A. Correct.

Q. So spread out over the two days?

A. Correct, right.

Q. And of those six to eight, how many are Gynemesh PS, typically?

A. I would say it may range from two to four.

Q. And with the understanding that, typically, it's going to be TVT Exact, how many are TVT?

A. Again, I would say as an average range two to four, it could be five. It could be four to five in a single day.

Q. So these are procedures that on a weekly basis you are discussing with patients and then performing, correct?

A. I would say on a daily basis, whether it's in the office or in the operating room, I am in constant, you know, dialogue, examinations that would involve these type of products, absolutely.

Q. So specific, and, you know, I guess we haven't said this, but is the Prolift on the market right now?

A. It is not.

Q. Why is that?

A. The manufacturer decided to withdraw the product from the market.

Q. Was there FDA action that preceded that?

A. It's my understanding that the FDA wanted to require very specific research at certain endpoints. Moving forward the company felt that they had already invested a significant amount of resources and felt that they had already adequately demonstrated what the FDA was asking for, but the FDA was not satisfied with what had been provided and wanted everything to sort of be redone.

Q. And, to your understanding, what did Ethicon do in response to that?

A. Again, I wasn't involved at that level in the decision-making itself. It's my understanding

that they chose to withdraw the products, the family of products on the market.

Q. Rather than perform the studies that the FDA was asking for?

A. I mean, I don't know that it's a rather than. They just decided to withdraw the products.

Q. And the defendants haven't made you privy to any of the internal communications regarding this business decision, have they?

MR. SNELL: Who? Answer to your recollection.

THE WITNESS: To my recollection, I don't remember being privy to that information, no.

MR. SCHNIEDERS: Do you have a --

MR. SNELL: Well, I mean, he has the 522 orders and the back and forth of what the FDA said, if that's what you're talking about. I should have objected because your question was a little vague. I wasn't quite sure what you were talking about exactly.

MR. SCHNIEDERS: I said internal -- you got real time right there, just read it. It says and the defendants haven't made you privy

to any of the internal communications regarding this business decision, have they, and I think the answer is no, to your recollection.

MR. SNELL: I don't know. I haven't looked through everything Ostergard has, and there's a huge binder, and if it's in his stuff, it's been given to him.

THE WITNESS: But, no, I have not.

BY MR. SCHNIEDERS:

Q. Okay.

A. In my recollection is that I have not. I don't recollect, rather. I'm sorry.

Q. And the most recent things that you might have read would have been Ostergard, correct?

A. I don't recall reading any of that in Ostergard, but, no.

Q. Have you asked the defendant for any of those internal communications?

A. I have not.

Q. Why not?

A. I don't consider them to be relevant to my generating the expert report.

Q. You're not curious what their decision-making process was in to why they wouldn't do

extra testing?

MR. SNELL: Form, foundation.

THE WITNESS: I have no curiosity in that domain. I have plenty of other work to occupy my time.

BY MR. SCHNIEDERS:

Q. But, as we sit here today, and we've established from your expert report you believe that, for instance, the Prolift is a safe product when used according to its indications, correct?

A. I think that we have over 3,000 clinical trials involving tens of thousands of women with data collected out to seven years that more than adequately supports the use of Prolift for the treatment of prolapse in women as an effective product, correct.

Q. But you don't know why the defendant pulled the product, if that's the case, correct?

MR. SNELL: Form, foundation, asked and answered.

THE WITNESS: I'm assuming like much in life, it was a business decision. They balanced potential revenue versus whatever investments, and but no.

BY MR. SCHNIEDERS:

Q. It was a money decision?
A. I don't know.
MR. SNELL: Same objection.
THE WITNESS: I don't know, sir. I'm sorry.
BY MR. SCHNIEDERS:
Q. We've established in the six to eight procedures per week, at least several of them are going to involve the products that you are testifying in this litigation?
A. That is correct.
Q. So take me through when you have a woman that comes in with pelvic organ prolapse and you've determined that Gynemesh PS would be a suitable surgical placement for her, what do you tell her about the risks and benefits?
A. Specifically, the discussion is the same. Women with prolapse have a certain set of baseline symptoms. Obviously, they have both symptoms, they frequently have bladder or bowel dysfunction. The majority of them have pre-existing sexual dysfunction. We explain to them the intent and the limitations of surgery in general in correcting those problems. I try to set realistic expectations as far as what is likely

to get better, what may not get better, and then we start to go through their options.

As I go through their options, I try to, in a fairly nondirective manner, to guide them to a decision based very much on the information that we're reading in my report. You know, these are the different procedures at our disposal. These are the different approaches. Some of these approaches may include hysterectomy or not hysterectomy. Some may involve simple tissue plication. Some are done abdominally, some are done vaginally, some are done as a combination of both. Some may involve the placement of mesh surrounding the vagina, and we go over what these women's priorities are, what their concerns are, what they hope to accomplish. We look at their ages, their co-morbidities, and I try to help them on an individual level to make a decision that's best for them.

Q. And on the topic of mesh and more specifically Gynemesh PS comes up, what do you tell them the risks are of that procedure?

A. Again, the conversation is largely, you know, all prolapse surgery come with very similar risks in terms of whether or not it will be successful, whether or not you will develop normal bladder

emptying, abnormal bladder emptying, could you experience chronic pain, could you experience pain with sexual intercourse. I can't tell you that I -- you know, I don't necessarily distinguish from one to the other in a general sense.

Obviously, if we're going to implant mesh, I speak to them about the fact that polypropylene mesh is the most widely used material in our field, that there's experience that goes back decades. That, in general, this is the consensus standard of care material used throughout the world, and obviously we talk to them a little bit about our personal experience in our practice and over my 24, 25 years of clinical practice.

Q. So when you're talking to a woman about placement of Gynemesh PS, do you tell her that it's possible that she will have chronic pain following the surgery?

A. To be honest with you, we rarely see pain as a consequence of these procedures. I certainly will say that there's always the potential for pain. Again, I don't believe that it's the mesh itself. To be honest with you, most of the pain that we see is certainly more related to the plication parts of the

procedure.

Rarely do I think the mesh has anything to do with that. You know, I think certainly if you look at the report, counselor, vaginal length tends to be longer when we use the mesh, sex tends to be more comfortable when we use the mesh. The incidence of pain is no higher than it is with the other techniques. The incidence of dyspareunia in most studies is extremely low, you know, certainly 10% is the summary incident that we will talk about. In randomized trials, it's been as low as 3%.

Native tissue repairs, in my opinion and in the literature that I've reviewed, often times have dyspareunia rates that are far higher, 15%, 25%. Again, it's a complicated discussion. The majority of these people have some degree of pain with sex prior to surgery. We have to speak about the likelihood that that pain will improve. There are some women that have no pain. We talk about the chance or the rates of de novo dyspareunia. It's not a black-and-white kind of discussion, and it's typically a discussion that takes place over three or four visits.

MR. SCHNIEDERS: I will object and move to strike as nonresponsive.

BY MR. SCHNIEDERS:

Q. Doctor, when you are talking to a women about placement of Gynemesh PS, do you tell her it's possible that she will have chronic pain following the surgery?

MR. SNELL: Objection. I think he's asked and answered that.

THE WITNESS: Okay. So the Gynemesh is only one part of the surgical procedure that I'm doing. So we are talking -- I talk to them about the overall risk of the surgical intervention. If we're going to do a hysterectomy and a sacrocolpopexy with mesh and a posterior repair, I'm talking about the overall likelihood of complications.

MR. SCHNIEDERS: Mark as Exhibit 10 the IFU for Gynemesh PS.

(Document marked for identification as Toglia Deposition Exhibit No. 10.)

BY MR. SCHNIEDERS:

Q. Doctor, are you familiar with this document?

A. I am familiar with the IFU, yes.

Q. For the jury's benefit, what does the

IFU tell a doctor?

A. The IFU stands for information for use. It's a document that will explain everything from the material you use, how it's sterilized what the intended uses are, situations in which it might be used. There is a listing of precaution and adverse events that are known and some suggestions to the surgeon to keep in mind when the surgeon is coming up with a surgical plan.

Q. And this is the 2015 version of this IFU because you understand that this IFU is updated February of 2015, correct?

A. That is my understanding, correct.

Q. Do you make it a habit as a surgeon to read the IFUs for all products that you're placing?

A. I am pretty much an instruction reader in general. I even read the instructions to my VCR and my phone, although, obviously, I missed the part about the voice speaking, but, yes, I am -- I do read, and largely, you know, I do teach, so I want to make sure that what I say is consistent with the IFU.

Q. Just excited you still have a VCR.

A. I know, right.

Q. If you go to the indications, what are

the indications for Gynemesh PS? It's on the second page.

A. With the understanding that as a surgeon, I've got the ability to use things as I see, you know, fit for what I'm working on. Specifically, we use Gynemesh for the correction of pelvic organ prolapse. What it says here specifically that it's being used as a bridging material for apical, vaginal and uterine prolapse. This one here that you've given me specifically, in my opinion, is referring to an abdominal approach.

Q. Okay. And was Gynemesh previously indicated for only an abdominal approach?

A. My understanding back in 2002, when Gynemesh -- Gynemesh PS received its indication, it was not stated in the same language, it was stated in a much more general sense that it could be used for prolapse, and the implication was either abdominally or vaginally.

Q. And is it your -- do you have the -- strike that.

Are you aware that that indication was changed at the same time that Prolift was removed from the market?

A. I'm aware through my review of these materials. I can't tell you at the specific moment that it was removed from the market that I was abruptly aware of that.

Q. So there wasn't an Ethicon rep that was coming by your office to let you know?

A. I mean, in general, I'm an expert in this area. I possess far more expertise than representatives. I can't tell you that I really depend upon the sales rep, in general. I know most things way before and beyond what any of the sales reps, so I cannot tell you that I have -- you know, that that's a -- where I depend upon the information from.

Q. But fair to say that the IFU is a document that's intended to give surgeons additional information about a product, including safety information, correct?

A. It's a document that provides guidance.

Q. If you go to the third page under adverse reactions, and I can mark the other IFU, if you like, Doctor, but if you have a recollection, do you recall that -- well, actually, let's just do it this way.

Strike that.

(Document marked for identification as Toglia Deposition Exhibit No. 11.)

BY MR. SCHNIEDERS:

Q. I'm marking as Exhibit 11 the previous IFU for Gynemesh PS, although I apologize that it's got a lot of other languages in there along with it. But the English version should be right out front.

So, Doctor, if you go to what we've marked now as Exhibit 11, that is the version of the IFU for Gynemesh PS that was in effect previous to this February of 2015.

Does that look consistent with your recollection?

MR. SNELL: Give me a second to look at it. Okay. Go ahead.

THE WITNESS: Sure. The date on here is September 15, 2008. I agree with you that this one preceded this one.

BY MR. SCHNIEDERS:

Q. If you look at the second page, would you look at the indication there for Gynemesh PS as of 2008?

A. Yes, I do see that paragraph.

Q. And that's a different indication than

what is in place in February of 2015, correct?

MR. SNELL: Foundation.

THE WITNESS: I would say the indications to me seem similar. The wording has been changed. In both they mention that the material is used for bridging material for the treatment of prolapse. One mentions vaginal wall. The other one is more inclusive of apical, vaginal and uterine. So, I mean, the language is slightly different. My opinion is the intent is pretty much the same.

BY MR. SCHNIEDERS:

Q. But the previous version of the IFU didn't infer an abdominal approach, correct?

A. Correct.

Q. Whereas the February 2015 IFU does, correct?

A. Correct.

Q. Okay. Doctor, if you go to the third page of both IFUs, you'll find the section that's called adverse reactions, and you can see just by looking at it at first glance, that the adverse reactions section in 2015 is much longer than it was in the previous version, correct?

A. Yes.

Q. And under -- in the previous version it states potential adverse reactions are those typically associated with surgically implantable materials, including infection, potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.

Did I read that correctly?

A. Yes, you did.

Q. And that's the only thing that's listed under adverse reactions in the previous IFU, correct?

A. Yes.

Q. If we go to the more recent IFU, I believe that that bullet point essentially that I just read with a few additional terms appears as the first bullet point in adverse reactions.

Does that look like a fair reading?

A. I agree.

Q. And then there's several -- there's eight more bullet points that follow in adverse reactions, correct?

A. Yes.

Q. And I missed two. There's two more on

the next page as well, so ten more, correct?

A. Yes.

Q. Okay.

A. Well, and then there are other adverse reactions, but I'm with you, counsel. I'm following along with you.

Q. Okay. So that second bullet point there that starts with "as with any implants," could you read that, Doctor.

A. As with any implant, a foreign body response may occur. This response could result in extrusion, exposure -- excuse me -- erosion, exposure, fistula formation and/or inflammation.

Q. And the third bullet point there that begins with "potential adverse reactions," could you read that?

A. Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain, pain with intercourse, which in some patients may not resolve.

Q. If you go to the bullet point that begins with "excessive contraction," could you read that, Doctor.

A. "Excessive contraction or shrinkage of

the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur."

Q. And what would happen if there was excessive contraction or shrinkage of the tissue surrounding the mesh?

A. I guess it would vary, depending upon where specifically we were talking about that.

Q. As the expert here, Doctor, tell me what are the different alternatives.

A. As the expert I can tell you I've never observed shortening or shrinking or scarring, but, again, I'm speaking to, you know, in the anterior compartment, there could be some influence on bladder function. At the apical end of things, I would think that it could affect sexual intercourse. In the posterior compartment, there could be events there, although, again, I point out in my report, I evaluated this extensively, and there's no evidence from the literature that these types of events are occurring with any greater frequency with these products as compared to other types of repairs, and that is inferred in the paragraph I believe that you read yourself, that these are risks typically associated with pelvic organ prolapse repair.

Q. Actually, that's the first paragraph.

A. Sorry. Third bullet point, "Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures."

Q. And obviously excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening is not something that is caused by pelvic organ prolapse, correct?

A. Pelvic organ prolapse or pelvic organ prolapse repair procedures?

Q. Fair enough. The repair procedure.

A. It is, and, again, if you read through my report, these are common adverse events that are associated. That's why it says that. It says potential reactions and it says typical, not unusual, typically associated with pelvic organ prolapse repair procedures. And, again, I have cited several very reputable sources analyzing over 100 studies involving 10, 11,000 patients suggesting low incidence of these things and incidences that are not any different than what is typically associated with pelvic organ prolapse repair that does not involve mesh.

Q. Regardless of whether it's caused by pelvic organ prolapse repair or by the mesh, you've

never seen it either way, right?

A. That's not what I've said, sir. I said that, in my experience, as I stated in my report, I've never seen the mesh cause shrinkage or scarring above or beyond what we would typically see.

Q. Do you see the second to last bullet point that says "neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur"?

A. I do see that.

Q. Do you agree with that statement?

A. I agree, yes, that with pelvic organ prolapse repair procedures that we do that those problems can occur. They can occur with suture based repairs. They can occur with mesh based repairs. If I could refer you to the study, and I'm sorry, some of these names I have trouble pronouncing, he did sacrospinous ligament suspension, Qatawneh, okay, he points out, for example, temporary sciatic neuralgia, this is on Page 15 of my report, pointed out that about I believe it was 11% of patients in either group experienced sciatic neuralgia.

Actually, Barber et al. in what's the OPTIMAL trial, and the OPTIMAL trial is included in the

materials I provided for you, and these were suture based repairs, nerve pain was observed in one arm, 6.9%, in the second arm 12.4%.

Q. Okay. In your risk-benefit discussion with a patient who is potentially going to have a Gynemesh PS placed, do you tell her that excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur?

A. Again, we don't do these procedures in isolation, so I speak to them about the total procedure. In general, that's not been our experience to see that, but I do explain to them that sometimes surgery can result in pain, either pain during sex or even pain not related to sex. And, obviously, they have an incision in the vagina. It's -- the incision is obviously going to be tender initially. That tenderness usually resolves over time; however, there are instances in which the pain will persist. I don't specifically say it's the product that causes those procedure because based upon the records -- excuse me, the literature that I have reviewed and my own personal experience in 25 years, that has not been what we have observed or is what's been reported.

Q. Do you tell that woman that potentially is going to have Gynemesh placed that neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg pelvic and/or abdominal area may occur.

A. I think that's what we just address, in general I tell them that is part of the risks of surgery in general for pelvic organ prolapse, that they are uncommon problems, and, again, if it's a patient with fibromyalgia, they probably have a little bit higher risk because they're already sort of predisposed to that. Again, it may vary based upon age. So it's really a general discussion that is sort of tuned for that individual, but, overall, I am covering the general topics as listed in -- that we've just been discussing from the IFU.

Q. But your discussion with women that are undergoing surgery to correct pelvic organ prolapse is the same, regardless of whether you're placing a mesh or you're doing any other surgery, correct?

A. Yes, because the risks are the same. Incidence of dyspareunia, pain, defecatory dysfunction, voiding dysfunction, incontinence, in general is not different percentage-wise between the procedures, and

that is sort of the sum and basis of the report that I've generated for this purpose.

Q. Do you tell a woman that potentially is to receive a Gynemesh PS product that at some point another surgeon or you may have to go in there and remove the mesh?

A. In general, I inform the woman that the mesh is permanent, that the good news is is that, typically, if we get a satisfactory result, that result is long lasting. I explain to them that typically the literature has supported that repairs done with mesh are typically superior to the results without mesh, and that certainly has matched our personal experience in this field in the last 25 years, but, yes, if they were to develop pain that there may be a risk of re-intervention. Typically, that risk of re-intervention is low in our practice. It's probably 5%.

The literature would suggest that the risk of re-intervention is in the low teens, again, depending risk factors. What's the patient's age, is she a smoker, is she obese. So sometimes I do fine-tune that and say I would consider you to be somebody at a little bit higher risk than what I'm explaining to you right

now or somebody that I believe are a little bit lower risk, but, again, it's always part of that general discussion about the surgery in general because we rarely go in and just sort of do one thing and nothing else.

Q. But it's fair to say that if mesh is never placed, that you don't have to go in and remove mesh if there's a complication, correct?

A. If mesh is not placed, then you don't have to go in to remove mesh. If suture is placed, you may have to go in to remove sutures, and, again, in our experience, those occur with equal likelihood.

Q. With sutures there's equal likelihood that another intervention would be necessary?

A. Correct. In fact, I published a paper in which the likelihood re-intervention to remove sutures exceeded 30%, and that is certainly -- that is probably three times the incidence of us having to go back to deal with mesh-related wound -- I'm just going to classify these are all types of wound complications. So whether the wound opens up, whether there's a suture that's exposed, whether the wound opens up and mesh is exposed, that's a wound complication.

In our practice and supported by the

literature, they occur at least with equal frequency. In our hands, they occurred three times higher with suture based repairs.

Q. Did you ever approach Ethicon and ask that Gynemesh's mesh be less rigid?

A. I don't know. I'm concerned because you seem to be reading from something while you're asking me that question, but I honestly don't know. I'm sure I offered them opinions, again, in a theoretical sense whether it was Prolift+M, whether it was Prolift, whether it was Gynemesh, there were subtle variations, there were other products from other companies, I may have had ideas about what I thought.

I mean, my recollection is that I said to them, look, at least in my observation, I find that, you know, Prolift+M is a more rigid material. At the time of implantation, that may be beneficial, it's a little easier to work with if it's rigid; however, it could, in fact, maybe be associated with more wound complications, and I would let them know that just so they can just include that in the information that they're receiving.

You know, again, I tended to be an early adopter of these procedures, and I felt a

responsibility as an early adopter to provide early feedback.

Q. What is your understanding of what a KOL is?

A. A KOL is a term that means key opinion leaders, and it's a term used by industry to identify people that they considered to be key opinion leaders. What they specifically mean by that and what I might think about that may not be the same thing.

Q. Would you have considered yourself to be a KOL for industry?

A. I mean, I think they might consider me to be a KOL. You know, I mean, certainly, at this point in time, I've been doing this for a long time, I do a high clinical volume, I'm a relatively straightforward and approachable person, and I'm pretty liberal with my opinions, but I would say -- sorry to give you a long-winded answer, I know that organizations have considered me to be a key opinion leader in this area.

Q. What is -- in medicine, what's a conflict of interest?

MR. SNELL: Form, overbroad.

THE WITNESS: Exactly. You know, I

mean, there are very many different forms of conflict of interest. I mean, you know, I'd have to get -- have a specific situation.

BY MR. SCHNIEDERS:

Q. Well, when drafting an article, is it part of the canon that physicians will disclose potential conflicts they might have that could potentially affect their opinion?

MR. SNELL: Form, vague, also undefined as to scope and time.

THE WITNESS: You know, I think there's a fine line between bias and conflict of interest, however, you know. For example, in the TVT Secur trial, I revealed to the publishing journal and the people reviewing the manuscript that, you know, yes, I have taught this procedure and I have been compensated for that time.

I'll tell you, quite honestly, I don't think the results of that trial was of any benefit to the company, you know. The company did not pay for that trial directly. It involved their products, so my involvement was based on my experience. My involvement was not

based upon the fact that I had a relationship with the company, but I understand that some people might view that as a negative, so I did disclose that.

BY MR. SCHNIEDERS:

Q. Well, what's the purpose of disclosing conflicts in literature?

MR. SNELL: Same objection.

THE WITNESS: You know, I think when you read something, you're trying to understand where that person is coming from and whether or not they may be otherwise motivated. You know, if I own stock in a company, I could run around and say -- you know, if I own stock in Volkswagen and I drove a Volkswagen, I might tell Bert and yourself and anybody else what a great car, I've never driven a better car, and I own stock in this company because I've got a conflict, in a sense. So that's how I would view a conflict. I might be otherwise motivated in revealing that information.

BY MR. SCHNIEDERS:

Q. As a physician, when you're reading literature how do you factor in potential conflicts?

A. You know, it's just one of a host of variables. Everybody clearly has a bias, you know, or a prejudice, you know, many of which might be based upon personal experience. So, you know, even if there's no industry related conflict, you know, there's always bias involved, and it's just one thing to keep in mind and it's a very -- you have to balance, you know, that with everything else that you're reading.

Q. And is that something that you as a reviewer of literature do when you're reviewing studies, for instance, in this case?

A. We look at their disclosures, you know. We looked at funding for the study direct. We look at what the authors would reveal as potential conflicts. I can't tell you that that is -- that commonly changes the overall value of the report or what's being said. The results typically speak for themselves. There are a number of internal controls.

So, for example, when you randomize somebody to one intervention or the other, you're looking to minimize bias. When you do a randomized trial that might involve over 50 surgeons across five different countries, as had been done, for example, with Prolift, you will also minimize those biases as well. When

things are blinded to the patient, you're trying to minimize the bias. If the patient knew that they were having the same procedure that maybe their sister had and their sister had a great result, for example.

Obviously it's a little harder to blind a surgeon. You can't blind them to do the actual procedure, I don't think that would be safe, but sometimes the person who is doing the evaluation of the result might be blinded to what the surgeon did. That was the case, for example, I believe with the TVT Secur trial, it was sort of single blinded in that regard.

Q. Is it significant to you when you review literature how much money one of the authors might have made from a company that that study benefits?

A. Typically, no.

Q. Is there a threshold where it does become important, for instance, if they make $500,000?

A. I'm not aware -- I don't have a threshold, no.

Q. So not a million dollars?

A. I don't have a threshold.

Q. $10 million?

A. I don't know how I can say I don't have a threshold any differently. You know, again, from

where I sit, as you can tell from my report, I'm more interested in the -- what we call sort of the summary or the pooled analysis of data. I'm not going to hold any single study as being the Holy Grail. I'm looking for consistencies between studies. I'm factoring in thing like biological plausibility to what's being offered. I'm looking very specifically at levels of evidence, you know, reproducibility of the results. Those are far more important to me than who was paid what for what and why.

Q. Who other than authors of a study should hold editorial power over the study?

MR. SNELL: Form.

THE WITNESS: You know, again, all studies are different. You know, some studies -- you know, if somebody is paying for a study to be performed, and, again, that's an arrangement made between the investigator and the source of the research, you know, for example, the NIH if they're going to sponsor a study, they oftentimes will insist that that study be available at no cost in a public forum to anybody who might want.

Certainly, in some of these studies that

were directly funded by the company, the company wanted to have access to those results. I don't know that it is common for there to be any undue influence, but, again, that sort of -- you know, you would think that once a study was published, it's sort of passed certain bars of professionalism to get to that point.

BY MR. SCHNIEDERS:

Q. Just so I'm clear because you just said after published, I'm talking about before it's published when it's still a draft manuscript?

A. Sure. I'm sorry. What I was saying if a study becomes published, you would assume this would have been vetted. It varies, it varies widely, you know, in our experience, as far as how much influence. Sometimes it's simply they want to be aware of the data. You know, sometimes they may want to contribute information. I'm not sure exactly what you're implying.

Q. I'm just asking is it appropriate for a pharmaceutical or a device company to have a draft copy of a study and add or subtract words from it prior to it being published?

MR. SNELL: Objection, vague, lacks foundation, incomplete hypothetical.

THE WITNESS: I think if -- I think that typically that is an agreement and a decision that is made before the study actually begins and, therefore, is kind of sort of removed from the actual results of the study, so it varies widely. You know, as an investigator you have to decide your level of comfort of that involvement.

You know, you appear to be maybe too young to have children in college, but it's the same argument, if I'm paying for my son to go to college, do I deserve to know, you know, his shenanigans, his grades, potential issues, you know. Again, there are agreements between you and your child, between you and the school, same thing in here. But those are usually clearly defined at the time that there's an agreement to fund the study and it varies.

BY MR. SCHNIEDERS:

Q. In your study that was funded by Ethicon, did they have editorial control?

A. My study was not funded by Ethicon.

Q. It wasn't?

A. Not directly, no.

Q. What do you mean "not directly"? That sounds like a qualifier.

A. My study was not -- again, I was not the study designer, but the study was funded by -- the funding is listed on the actual study, I believe it was the foundation, and I'm sorry if I'm forgetting the exact terms, the foundation of women's health. I did not receive any compensation, and I don't -- it was founded by the foundation, and it was a randomized study between seven sites. So I would violently object to you telling me that that study was funded by Ethicon because it was not.

Q. And not sure if I'm clear, are you saying you didn't get compensated at all for that study, or you didn't get compensated by Ethicon?

A. I was not compensated by Ethicon for that study.

Q. But the foundation, they compensated you, right?

A. The -- excuse me, the study compensated my practice for the data collection and the clinical nurse coordinator and stuff like that.

Q. Did you get paid anything yourself?

A. I mean, in my employment all monies go into a pool. We subtract expenses from revenue. The money doesn't come to me directly labeled or traceable from any one site.

Q. So, clearly, if Ethicon didn't fund your study, it would be inappropriate for them to have a draft copy and make edits on that, right?

A. Those are two completely separate issues.

Q. How so?

MR. SNELL: Objection, asked and answered.

THE WITNESS: Again, I was not part of the -- that discussion. I did not discuss the study with Ethicon. I don't -- was not part of that discussion. My understanding is that they saw a copy of the results. I do not believe that they had any influence. I will tell you that that particular study won two first prizes as best surgical paper of the year, both one nationally, one internationally. That is not something that occurs with an industry -- you know, an industry sponsored study.

BY MR. SCHNIEDERS:

Q. So that was not an industry sponsored study, correct?

A. Again, I was not -- I did not design the study. I am not employed by the foundation that I mentioned, so that was not directly funded by Ethicon. The foundation collects money from various sources, including people like myself that would make a contribution. The pooled resources of the foundation funded studies. The studies were designed by the investigators. The company had no influence on the study design. The company had no influence on the study results. The company had no influence on the writing of the manuscript and they certainly had no influence in the presentation or the submission of the data. I hope I've clarified that for you because you seem to be a little misinformed in that regard.

(Document marked for identification as Toglia Deposition Exhibit No. 12.)

BY MR. SCHNIEDERS:

Q. Doctor, I'm showing you what I'm marking as Exhibit 12, which is a PowerPoint that came from Ethicon and it's entitled "KOL Strategy."

A. Uh-huh.

Q. So a moment ago when we were talking about KOLs, we discussed the fact that that means key opinion leader within the industry, correct?

A. That's my assumption. I can't tell you that anyone has ever -- I've kind of figured that out myself. Obviously, it doesn't stand for Knights of Columbus, but I'm assuming that that's what that means. I have no objection if you tell me that that's what that means.

Q. That's my understanding as well.

If you see on the front page of this, this is from February of 2008, you see that?

A. And this is coming specifically from where?

Q. This is from Ethicon.

A. But where specifically within Ethicon? This is marketing, this is R&D, this is --

Q. We would have to get the Bates number and tell you whose file it was in, but it's from one of their internal files.

A. Sure.

Q. So if you go to the third page -- probably marketing, typically.

A. I would agree with that. I'm sorry that

I led you to that statement.

Q. Typically, KOLs work with marketing, right?

A. I mean, I was a KOL that worked -- like, my involvement, say, with Astellas, which is more Astellas global international, my involvement is not marketing. It's more R&D, and, you know -- and as we've been discussing, much of my relationship and interest with Ethicon has been R&D.

Q. So if we got to this third page that says "KOL Categorization," there's a circle with several other circles surrounding it?

A. Yes.

Q. It starts off it's got the KOL here in the middle in the blue circle, and then it's got all these different categories, it appears, that whoever put this PowerPoint together feels fall within that KOL categorization.

You see that?

A. Yes.

Q. And there's things like society or influencer, expert user, advocacy/PR, faculty. Are those all things that you've seen in other KOLs that were with Ethicon as well as you?

MR. SNELL: Foundation.

THE WITNESS: You know, I got to be honest with you, I was not someone that was, you know, involved at all levels. I did my little piece and stuck to my little piece. To me, I look at this, and I'm like, what is a KOL? Well, a KOL could be any of these things, or all of these things would contribute to a KOL. You know, some of these people could be physicians, advocacy, could be some of these advocacy groups that are out there, the incontinence -- National Incontinence Society.

BY MR. SCHNIEDERS:

Q. Do you consider AUGS to be an advocacy group?

A. AUGS is an advocacy group, yes.

Q. If you go to next page, there is a title that says "Objective," and there it says, "Engage KOLs across the spectrum of functional expertise to partner with EWH&U in supporting organizational objectives."

Did I read that correctly?

A. You did.

Q. And EWH&U stands for Ethicon, correct, women's health?

A. It stands specifically for Ethicon women's health and urology.

Q. So the group putting this together at Ethicon feels that KOLs can be brought in in order to support organizational objectives, correct?

MR. SNELL: Calls for speculation.

THE WITNESS: Again, you know, my role -- and, again, my role as a KOL person of influence was infinitesimal. I was not as -- as they would say, I was not in the starting lineup. You know, I take it for what it reads, that the objective of this project was to engage KOLs across the spectrum, meaning that we're not just going to focus on surgeons, you know, we're just not going to focus on inventors. We're looking for a broad range of individuals that might be able to help us.

BY MR. SCHNIEDERS:

Q. If you keep going, skip the next page, next two pages actually and there should be something that says "Categories" at the top. There you go.

A. Yes.

Q. And it's got several different specialities, for lack of a better term.

A. Sure.

Q. The top one is "Incontinence/Pelvic Floor Specialist (UroGyn, GYN)," and of these groups, and you can look at it, by all means, but that's probably the group that you would identify most specifically with, right?

A. Yes.

Q. If you go to the next page, it starts off with -- it's got a title, it says "Incontinence (UroGyn, Gyn)," and then it's got different categories, as you can see, in the top. It's got "Prof Ed Faculty," which is professional education, right?

A. Yes.

Q. And under that it says "National TVT Preceptor," and you're at one point a national TVT preceptor, weren't you?

A. Yes, I do believe that I was categorized as a national preceptor.

Q. And there's a category called "Published," and under that it says "Published in peer reviewed journals." Is that read correctly there?

A. I'm sorry. I was looking at a different page, and I apologize for not paying attention.

Q. So right next to Prof Ed, there's a

category called "Published."

A. Yes.

Q. And under that it says -- under where it says "Description/Criteria," it says "Published in peer reviewed journals." Did I read that right?

A. Yes.

Q. And then if you go all the way, there's "Academic" and then there's "Inventor."

A. Yes.

Q. And there's "Emerging," and then there's "Expert User."

A. Okay.

Q. And "Description/Criteria" is "High utilization of product (EWH&U and Competitive)."

Did I read that correctly?

A. Yes.

Q. Okay. And what does that mean to you as far as high utilization of product?

A. My interpretation is given that this was a marketplace that had 49 slings, my interpretation is that if 99% of what you did in this sphere was with our product, as opposed to I dabbled with everybody's product, I would interpret that to mean, you know, that that's where high utilization.

Q. And then there's "Advocacy/PR/Policy" and the criteria there is "Practice in top 25 media market, academic/society affiliation," and last one is "Society Leadership or Influencer, leadership role in AUA, AUGS SUFU" --

A. Sure.

Q. "AAGL, ACOG, General Influencer."

A. Uh-huh.

Q. If you go to the next page, then it puts some names here with the group. I'm sure you're shocked by that.

A. I have no vested interest and could care less. This is their opinion. It means nothing to me. I could care less where -- I'm just laughing as far as, you know, they have me listed as an inventor, you know.

Q. They do?

A. Yeah, see that.

Q. They have you listed under inventor actively engaged in the creation of new products?

A. Right. How come I'm not in the top ten?

Q. And then -- well, you are in the top ten on several of these.

A. No, I'm not. Not on this one I'm not. This is TVT.

Q. Under "Expert User, High utilization of product," you're actually in bold there, if you see that down at the bottom?

A. I have no idea what that means. I'm actually on that list twice.

Q. You are, you are.

A. Yes, I don't know. I mean, again, I don't know how to interpret this, in all fairness. Competitive in my mind is, you know, maybe Boston Scientific would be interested in this person, so this is somebody that, you know, other people might be of interest. That's how I would look at competitive.

High utilization, I mean, you know my history with the company, I've used their products extensively, more so than any other things. So to me that speaks to the fact that I was an early adopter, and I've remained engaged throughout that period of time. That's how I look at it.

Q. And if you look at this across the way, then you'll see that there's probably some names that are very familiar to you as well?

A. I will tell you almost everybody on this list is familiar to me.

Q. And specifically Vincent Lucente who is

someone that you are a colleague of here in the area, right?

A. Yes.

Q. And then I believe that in that same column there, Mickey Karram was an author along with you in your study?

A. Correct, right.

Q. Under academic I think Dr. Iglesia was an author with you as well?

A. Yes.

Q. Sokol is that someone that you're familiar with?

A. Well, that's an interesting thing. The Sokols are twins, and they are both urogynecologists, and this does not distinguish which Sokol we're talking about.

Q. Both of them happen to be defense experts in this litigation, so it could be either one of them.

And then if you go across --

MR. SNELL: Who for?

MR. SCHNIEDERS: I don't know the answer to that.

MR. SNELL: I didn't know that. That's

news to me.

THE WITNESS: I'm sorry. Are you testifying?

MR. SNELL: No, he made a statement on the record, so I want to understand it. I don't know if Eric and the other Sokol are experts, whatever.

MR. SCHNIEDERS: I can find out for you. I was told that they were.

BY MR. SCHNIEDERS:

Q. And then over on the far right, you see that there are some members of the various advocacy groups, AUA, AUGS. Do you see over there, do you know Rebecca Rogers?

A. I do.

Q. Do you know Dee Fenner?

A. I do.

Q. Do you know Anton Bueschen?

A. I do not.

Q. John Barry?

A. I do not.

Q. Are you a member of AUA?

A. I'm not a urologist. I am not.

Q. But fair to say that there's many names

on here that you're familiar with and that are colleagues of yours, correct?

A. They are. Again, I don't know the context. I don't know that this is just simply a list of people to be aware of. So Rebecca Rogers probably at the time that this was published was the president maybe of AUGS. Maybe this is someone that they just want people to be aware of the names or if they saw them, they would introduce themselves. Maybe this is somebody that they were hoping to have a better relationship with. I think -- I mean, the fact that they considered me to be an inventor I think they're being very generous or liberal in how they're -- I think they're just categorizing people, which is certainly innately human to take things and put them into nice little boxes.

Q. Interesting. But as of February of 2008, you had done some consulting with Ethicon, hadn't you?

A. I had, yes.

Q. And if you go there's several pages of these types of categories, the one I was reading off of was "Incontinence." The next one is "Incontinence (Urologist)," and then after that there's a section

called "Pelvic Floor Specialist," which is also a specialty that I believe you would probably hold yourself out as holding, correct?

MR. SNELL: Form.

THE WITNESS: You know, I mean, the specialty has gone by many names. I think here they were trying to be inclusive, you know, of urology, at the time what we called urogynecology, colorectal, perhaps.

BY MR. SCHNIEDERS:

Q. But if you look at the page where you'll have some names that are pelvic floor specialists on the next page from where you are, I believe, you made the list. You're an expert user down there?

A. I am. Where am I? Oh, there we are.

Q. Third from the bottom down there.

A. It's a miss -- I don't know who Dr. Tolia is, but that could be me.

Q. I think it's you.

A. I would not object to that.

Q. And do you know a Dr. Fagan?

A. He was my partner.

Q. That would make a lot of sense.

A. Yeah.

Q. And then there's some other names that we saw on the other page, but then there's a couple new ones under "Published" and "Academic." You see a couple that are Goldman.

You see that?

A. On the same page?

Q. On the same page. If you go to "Published," the second -- sorry, the third name down and on "Academic" is Goldman?

A. Yes.

Q. Do you know Howard Goldman?

A. I do.

Q. Howard Goldman was one of the authors of the AUGS mesh statement, correct?

A. I will accept that if you tell me that, yes. I don't have a visual picture of the author list.

Q. And just so --

A. Are we certain that that's the same Goldman? It's fairly common.

MR. SNELL: How about object, foundation. Go ahead and lay that for me.

BY MR. SCHNIEDERS:

Q. So to spell it out for all of you, my next question on the next page under "Expert User,"

it's spelled out as Howard Goldman. What is the group CCF? Do you know what the group CCF is?

A. I can guess. I can't tell you that I recognize those initials.

Q. Well, I'm not going to hold you to it. I'm just curious, can you guess for me?

A. My guess would be Cleveland Clinic Foundation.

Q. And does Howard Goldman work at Cleveland Clinic?

A. I believe so.

MR. SNELL: Can we take a break in a minute?

MR. SCHNIEDERS: I'm switching topics, so let's take a break.

(Brief recess taken at 5:02 p.m.)

(Deposition resumes at 5:12 p.m.)

BY MR. SCHNIEDERS:

Q. I'm going to mark as Exhibit 13 an e-mail chain that you were included on, Doctor.

(Document marked for identification as Toglia Deposition Exhibit No. 13.)

BY MR. SCHNIEDERS:

Q. Do you recall earlier when we were

discussing the concept of whether or not funding from industry or other funding might lead to a conflict of interest.

Do you recall that discussion?

A. I do.

Q. Okay. You can take a minute, if you want, to read that bottom e-mail so you have some context here, and I'm going to ask you if you recall this?

A. I mean, I'm aware of the -- you know, the discourse between two of my colleagues. Are you asking me specifically am I aware of the e-mail or just of the circumstances?

Q. Either one.

A. I'm aware of the circumstances. I don't recall whether this was covered in the TVT deposition or not.

Q. You guys covered a lot of stuff that never made it to the record, and that's impressive.

You were on this e-mail?

A. Well, I was copied on this e-mail, okay, right.

Q. Right. And what, to your knowledge, was this consternation about?

A. If I remember correctly, and this, of course, is going back for six years, and this is a relatively minor issue that I think Dr. Iglesia had either responded in a letter to the editor, it could have even have been -- you know, when we present things at national meeting, we allow people to get up, make comments, suggestions. So in one of these forums, she was trying to -- and I can't remember which way it went, whether it was Lucente initially commenting to Iglesias on her work or whether it was Iglesias commenting to Lucente, but all I can tell you is that I recall that there was some friction and really just collegial -- or not collegial, but discourse between two colleagues about that interaction.

Q. Fair to say that Dr. Iglesias inferred that Dr. Lucente's superior outcomes were perhaps due to financially driven bias?

MR. SNELL: Objection, calls for pure speculation what somebody else thought.

THE WITNESS: I don't know. I'm sorry, but I don't know what study or whether this was written comments, comments in the cafeteria, comments with someone on the podium.

BY MR. SCHNIEDERS:

Q. Do you know why you would have been included on this e-mail?

A. I don't, no.

Q. And Dr. Lucente is a colleague of yours. Do you consider him to be a friend as well, or is it somewhere in that blurred line?

A. I think it's fair to say that -- I've known Vince since he was a fellow, so we go back at least 25 years. Vince is certainly both a colleague and a friend of mine, as is Dr. Iglesias, who I've known for about the same amount of time as well, I knew her when she was a fellow as well.

Q. Fair enough. Set that to the side.

A. You understand that Dr. Lucente and I are both Italian, and so sometimes that may influence the tone in which we respond to other people, and we're both from New York.

(Document marked for identification as Toglia Deposition Exhibit No. 14.)

BY MR. SCHNIEDERS:

Q. Give you what's been marked as Exhibit 14. Unfortunately, this is the method by which we get this information a lot of times. I want you to look at this, and I'll give you an opportunity if you need to

vet it in any way, shape or form as I go through some of these, but I will tell you if I found one that's a duplicate, but this is a report that was given to us as part of a larger spreadsheet and it's been reduced just down to your name instead of the thousands of columns and everything like that, and it shows that from March 1st of 2008 through February 2nd of 2010 that Ethicon paid you $152,000.

Do you have any reason to dispute that?

MR. SNELL: I'm going to object. That is purely without foundation. You're making a bald-faced assumption based on contract amounts. Do not make a statement on the record that Ethicon paid him that amount of money without proper foundation. And this was explicitly covered in the first deposition too.

MR. SCHNIEDERS: I've got several of these.

MR. SNELL: You know how much he was paid. You know how much he was paid. You have the productions of how much he was paid.

MR. SCHNIEDERS: I have this.

MR. SNELL: No, no, no. You have the productions of how much he was paid in each

year.

MR. SCHNIEDERS: Make your objections.

MR. SNELL: Don't make a ridiculous -- lacks foundation.

MR. SCHNIEDERS: Then make the lacks foundation objection.

THE WITNESS: I don't -- I never received $81,000 from Ethicon in any given year. If I looked at this, I would say it's more like the number to the far left. I mean, I don't know what the two columns mean, but to be honest with you, and we did cover this in the other deposition, you know, the most I ever got paid from Ethicon in a given year might have been $31,000, but, no, $81,000 no; $45,000, no.

BY MR. SCHNIEDERS:

Q. Okay. So this is incorrect, this spreadsheet?

A. I don't know what this represents, so how do I say if it's correct or incorrect. I just see numbers on a page. I don't -- and I'm being very honest with you, that does not resemble anything in my working memory.

Q. Okay. So, sitting here today, your testimony is that $152,000 for that time period doesn't look like that was the right amount?

A. Over the course of two -- over the course of two years.

Q. From March 1st of '08 through February 2nd of 2010.

A. No, this suggests that between -- that between -- right, March 1st of 2008 to March 1st, 2009 they paid me $81,000, no, no, not even -- not even -- no.

Q. You dispute that amount?

MR. SNELL: He already told you.

THE WITNESS: Yes.

(Document marked for identification as Toglia Deposition Exhibit No. 15.)

BY MR. SCHNIEDERS:

Q. I'm going to mark as Exhibit 15 the next spreadsheet we had for this. I actually handwrote the Bates number on that one since they come from the Excel spreadsheet.

This one covers -- and it just had end dates on this spreadsheet, but the end dates are September 23rd of 2010 through November 5th of 2011, and that covers

$153,000. As you can see the requesters, the contract amounts are different than what you just saw, as are the dates. So is it your testimony -- that in 2010 and 2011 that this $153,000 is incorrect?

MR. SNELL: Form, lacks foundation.

Go ahead.

THE WITNESS: I honestly don't recognize any of this. I can tell you that often times in the contract, there was a ceiling, so it would say something like, in a given year, you know, your compensation will not exceed, and so these numbers like $30,000, $10,000, in my mind, might have been a ceiling. I just, you know, I mean, if you said to me, you know, in your relationship with Ethicon between 1999 and 2011 was your total compensation the 153? I mean, maybe. I mean, is this just accounting on how they sort of -- but, yeah, I don't know.

BY MR. SCHNIEDERS:

Q. That's fine. I just want to get your testimony on it. That's fine.

MR. SNELL: You've already testified in the first deposition.

THE WITNESS: Yes, I did. Okay. That's

fine.

MR. SNELL: You don't have to accept it.

MR. SCHNIEDERS: Nobody is accepting. I said all I said we're doing is getting your testimony.

THE WITNESS: That's fine.

(Document marked for identification as Toglia Deposition Exhibit No. 16.)

BY MR. SCHNIEDERS:

Q. Exhibit 16 is Master Consulting Agreement. This one covers the time period that starts on February 1st of 2011 and ends on March 31st of 2012. It may have been a few years since you've looked at one of these doctor, but if you go back to Exhibit A, that's where it talks about what the fees are associated with it?

A. I'm sorry. Would you mind giving me a few more minutes to just --

Q. If you look at Exhibit A, there's boxes checked that cover this contract right here, and the first one is --

A. I apologize. I'm not with you. Can you tell me again where you are.

Q. Exhibit A.

A. Sure.

Q. It's about three-fourths of the way through this, I would say. The bottom number on the Bates number ends with 167.

A. Yes, okay. Sorry. Go ahead.

Q. Under A it says, "Consultant agrees to perform the Services below for which the 'Yes' box is checked for the compensation set forth therein." Company-sponsored speaker programs is checked yes, and then if you read through there it says, "Consultant shall present scientific, clinical and related professional information by speaking at Company-sponsored seminars and meetings as requested by Company. Consultant shall disclose to attendees that he is being compensated by Company for the presentation. Consultant shall make such presentations on 8 occasions. The presentation will review stress urinary incontinence procedures. For each such speaking engagement, Company shall pay consultant $3,000 per 8 hour day plus reasonable out-of-pocket expenses.

And I'll tell you that eight times 3,000 is $24,000. It says no under Subsection 2. It says no under Subsection 3. Under Subsection 4 it says

"Preceptorship/Surgical Training, yes. Consultant shall allow visiting surgeons and visiting Company sales representatives to observe surgical procedures involving the practice of stress urinary incontinence, the clinical uses of stress urinary incontinence family of products and to consult with Consultant regarding such procedures applicable to patient confidentiality and consent requirements. In particular, Consultant agrees he or she shall secure appropriate patient consent to the presence of any third party during surgical training programs as necessary. Consultant shall allow such visits up to 9 occasions, and Company shall pay consultant $3,000 for each such session per 8 hour day."

And that adds up, if you take nine times 3,000, to 27,000.

If you go to the next page, it's checked no on Number 5, 6, 7. On 8 Other, it's checked as yes, and it says, Consultant shall perform other services designated below for, and it has a dollar sign and it says varies per hour, and the description of services is faculty training meetings and educational summits/forums. Negotiated rate to be no more than a maximum of $375 rate/per hour.

And then it goes down to say "B. The parties agree that compensation paid to consultant shall not exceed $54,000 per contract term, except as may be mutually agreed in writing by the Parties."

Do you see that?

A. Yes.

Q. Do you recall this contract?

A. Yes.

Q. So with counsel's caveat that these -- saying that these are agreed maximums, not payments that are made out, I'm keeping a running list of these amounts here.

A. All right. Can I point out that the numbers you provided on this list for the period of time covered in this contract greatly exceed this $54,000, which is one of the reasons why I don't believe that this represents actual compensation.

Q. Sure, but you can also point out the fact that the dates and contracts often coincide at the same time because there's different consulting agreements that you signed at different times with different people, correct?

MR. SNELL: Form, foundation.

THE WITNESS: Can I disagree with you,

because this document specifically refers to this as a Master Consulting Agreement, and everything on this list right here is designated under the Master Consulting Agreement. So these two documents don't agree. I mean, this is a completed document, and I have recollection. I have no idea where these numbers came from.

BY MR. SCHNIEDERS:

Q. Fair to say that you don't believe in any given year you made over $100,000 from Ethicon?

A. I think $31,000 was the highest I made, and I will tell you that that was when we were working on the PASS study. That had nothing to do with other stuff.

(Document marked for identification as Toglia Deposition Exhibit No. 17.)

BY MR. SCHNIEDERS:

Q. I'll keep going through and you can disagree with me on the numbers, that's fine, I'm just putting them on the record. This is 17.

A. Fine.

Q. And this is part of an e-mail that is titled Action Required with some numbers 2012 Master

Consulting Agreement, Marc Toglia, MD, Incontinence Annual, and it's some other contract numbers there.

It says under here under line items, Number 1, Marc Toglia, MD, and then it says consulting fee. It's got a contract ID number, which if you want to reference it on the spreadsheet over there doesn't show up anywhere, and it's got an amount of $14,250. I'm not asking if it's accurate. I'm asking if I read that correctly.

A. This is for 2012. I don't recall receiving -- I don't know that I received any compensation from them. I think this might be the amount that I was approved, the maximum amount. I have no idea. I have no idea what this refers to.

Q. And you see down at the bottom that the total cost of this contract is $15,000.

Do you see that?

A. Yes.

Q. You can set that to the side. Give you what I'm marking as Exhibit 18, which is another consulting agreement.

(Document marked for identification as Toglia Deposition Exhibit No. 18.)

BY MR. SCHNIEDERS:

Q. This takes a slightly different form than the one we were looking at that was the master agreement, correct?

A. Yes.

Q. Although, if you go through, you'll see that when it gets to the third page, it starts to look a little bit more like the Master Consulting Agreements that we've seen before. On this one the agreement shall commence on April 1st, 2012 and then it goes through March 31st of 2013.

It is nearly identical in content. If you go to the page where you signed it, you signed it on February 6th of 2012.

Do you see that?

A. Yes.

Q. And Paul Parisi who is countersigned, do you know who Paul Parisi is?

A. He is an individual that worked for Ethicon.

Q. And on this one on the Exhibit A, it appears that there was a yes checked next to company-sponsored speaking program again, and it was for one occasion for $3,000, and then the Number 4 the preceptorship/surgical training was checked as well,

and that was for four occasions at $3,000, and then moving to the end, everything else was checked no, and "The Parties agree that compensation paid to consultant shall not exceed $15,000 per contract term, except as may be mutually agreed by the Parties."

Do you see that?

A. Yes.

Q. So I will tell you that I have gone to add up the amounts, and the amounts that I've added up from the spreadsheets and from these contracts we've been looking at after going through to make sure that the contract numbers didn't duplicate was $389,000?

A. Sir, this was --

MR. SNELL: You got to let me object. Objection, lacks foundation.

MR. SCHNIEDERS: Everybody has to let me ask my question first. That's how this works.

THE WITNESS: Fair enough.

BY MR. SCHNIEDERS:

Q. I have gone through and added up the amounts from the spreadsheets and from the contracts and made sure that they didn't duplicate any contract numbers, and it comes up to an amount of $389,000. I think what you're going to tell me is that you were

never paid $389,000 from Ethicon?

MR. SNELL: My objection is lacks foundation, misstates the evidence.

THE WITNESS: What do you think that number represents? I don't understand. That was the maximum that I could have done. I can tell you, say specifically the first thing talked about giving presentations at a national meeting, or, you know, I can't -- other than -- I can't tell you that I ever was asked to give that kind of a presentation. So even though it says I could have given that presentation, pretty much the only thing that I ever did in prof ed was teach cadaver labs, which maybe occurred once or twice a year, okay, or I precepted an individual, which, on average, may have occurred two to six times a year. That was probably -- you know, again, this might have been an allowance. You know, the company was approving a maximum amount. That does not reflect what I was paid by the company.

BY MR. SCHNIEDERS:

Q. I think you said, I just was looking at the record, you said that probably the most you ever

got paid in any given year was 31,000?

A. My -- yes, my recollection from the earlier deposition, and, again, this may not be accurate, my recollection was that in 2011, I received $31,000, and my recollection is that that related to the period of time that I was working on product development. It did not reflect preceptor time, lecturing time. That was never a big part of my role with the company.

Q. Okay. I'm going to mark as Exhibit 19 this e-mail string.

(Document marked for identification as Toglia Deposition Exhibit No. 19.)

BY MR. SCHNIEDERS:

Q. We can certainly look at the top e-mail here in a moment, but it doesn't pertain to what we're here to talk about, but if you go down to the bottom, Ronald Horton writes an e-mail.

Do you know who Ronald Horton is?

A. No.

Q. But it says he's with ETHUS, which I believe is Ethicon US. He's written it to a Marti Heckman, Alyson Wess, Lissette Caro-Rosado, Paul Parisi and Matt Henderson.

A. Right.

Q. Now, we've already talked about Paul Parisi.

Do you recognize any of those other names?

A. Vaguely.

Q. And the subject is KOL Usage, which, as we established before, is a term used in industry?

A. Yes.

Q. And it means most likely key opinion leader, and Ronald Horton writes, "All, please see the below list of highly used KOLs and the total pay they have received this year." This is written on Friday, November 19th, 2010?

A. Uh-huh.

Q. And if you look at the second page, it says Toglia total, $153,000.

A. No.

Q. So someone at US group product director for uterine health, Ronald Horton believes that you were paid $153,000 in 2010?

MR. SNELL: Object on the foundation, calls for speculation. Also, I think this e-mail was marked and covered in the earlier deposition, but go ahead, tell him what you

think about that.

THE WITNESS: I'm sorry. Me tell him what I think about --

MR. SNELL: You can answer. I'm not sure if there's a question. The question was so someone at US group, product director Ronald believes you were pay $153,000.

MR. SCHNIEDERS: In 2010.

MR. SNELL: In 2010.

THE WITNESS: I'm pretty confident that I didn't receive anything like that, sorry.

BY MR. SCHNIEDERS:

Q. So this e-mail is just wrong?

A. I don't know, sir. I was not part of this e-mail.

Q. Well, I understand that, Doctor. What I'm saying is it says that you were paid $153,000 in 2010. You're saying you weren't, so it's wrong, right?

MR. SNELL: Lacks foundation.

THE WITNESS: Yes, I'm telling you that I did not receive that compensation.

BY MR. SCHNIEDERS:

Q. Does that mean that your group received that compensation?

A. No.

Q. Did anyone on your behalf receive that compensation?

A. No, not to my knowledge.

MR. SCHNIEDERS: Marking as Exhibit 20 this e-mail string.

(Document marked for identification as Toglia Deposition Exhibit No. 20.)

BY MR. SCHNIEDERS:

Q. I'll let you familiarize yourself with it, the e-mail from Joy de los Reyes on down is the one I'm talking about. The very bottom one is an e-mail from you.

So, Doctor, this is an e-mail that you wrote from your e-mail address that we will make sure doesn't show up anywhere it's not supposed to, to Melissa Chaves.

Are you familiar with Melissa Chaves?

A. I recognize the name. I honestly can't -- I don't know what role she plays in the company.

Q. The subject is "thanks," and it says, Melissa, I wanted to thank you again for including me on the sling discussion panel yesterday. I very much

enjoy working on these types of panels and did appreciate what the others had to say on the other approaches. It's fascinating how different approaches work equally well in different hands. Thought it went very well, and I received a lot of positive feedback afterwards from the audience. I think that everyone felt that it was fairly balanced, and several folks mentioned that they were glad to see that Ethicon is still very much supportive of the retropubic design, as many feel it is still your best product.

That said, it has occurred to me that your company spends virtually no time on TVT-R training, and this is something you may want to consider revisiting, especially as you look to bring surgeons back to the TVT family of products.

Now, when you said "bring surgeons back to the TVT family of products," what did you mean?

A. Okay. So my recollection of the contents of this discussion is that Ethicon held a meeting of faculty members. As part of that meeting, they asked three of us to volunteer to do a debate-style discussion. I represented the retropubic approach. Another doctor represented the obturator approach. The third doctor represented the TVT Secur

approach. They then presented us with a patient case and then asked us to defend why we would choose whatever approach we were assigned to. My recollection is that I was assigned to the retropubic approach. It was kind of a debate style amongst colleagues. Everybody I thought did a very good job of defending the position that they were asked to represent.

Again, it was a -- it was a debate so we were just asked to defend our position, and at the end of that debate, people commented to me that they thought that my argument for that particular case for the debate was very convincing. As you well know, the majority of what I do in my clinical practice is the TVT retropubic approach. As my expert report previously illustrated, I believe that that is the product that has the most data of any procedure for incontinence in our history and that that represents very solid data, and so obviously I feel very strongly that that is the procedure of choice. That's my opinion.

So I was commenting to them that, you know, my opinion was that they should spend more time, you know, training and talking about this thing, and I just simply told them that I would be happy to participate

in further -- they wanted to invite me to give a further debate or another talk in front of my colleagues that I enjoyed participating in that type of activity.

Q. So you wrote this in order to help Ethicon bring surgeons back to the TVT family of products, right?

MR. SNELL: Objection, misstates.

THE WITNESS: No, no. I just -- you know, I just thanked them. I was not paid separately to participate in the debate. I was just thanking them for thinking of me as a -- as somebody who could speak in a debate fashion on this topic. And, again, my feeling was is that the TVT sling had the most data out there relative to other retropubic products, and I felt quite confident that this was the product that was -- according to the data, had the most efficacy and safety and just, you know, the amount of data presented and that I thought that they -- if they focused on presenting that data the way that I did in the debate, that hopefully others would also see that the TVT is the best procedure based upon sound science for

the treatment of stress incontinence across the entire spectrum of the disease, mixed incontinence, plain stress incontinence, repeat surgery, et cetera.

Q. And you wrote here, "Certainly, users of other retropubic products could be persuaded, and perhaps those using obturator approaches could be asked if they would like to add the retropubic approach for their more complicated patients, (eg expand upon their skill set, now that they are comfortable with TOT.) From there, it might be easier to re-explore the possibility of them using your brand of obturator sling."

So it's a sales pitch, right?

MR. SNELL: Objection.

THE WITNESS: I was speaking to a salesperson. I again was trying to use language. I don't sell anything myself. I have no vested interest in what they get revenue wise. I certainly don't see any of it. I was just defending TVT retropubic as the gold standard in our field and just wanted to let them know that I thought that that was -- you know, in my opinion, as a minor player, you

know, in this world for them, that this is where I thought I was most passionate about, and, again, I was speaking to the data and the science, that to me this was a no brainer. You know, you should try to reengage people based on the science and the data.

Q. And you offered to do a dinner talk on the merits, correct?

A. Yes. That might have been with other members of her team. I don't know.

Q. Sure. But you're compensated for dinner talks as a teacher, correct?

A. If I was speaking to -- I mean, I was not -- like I said, I was not compensated for this participation. If I had dinner with them locally, I don't get paid for that kind of stuff. Again, I'm just an advocate for the TVT retropubic approach. I thought that I made a strong argument why the data supports the retropubic approach as the best procedure. I got a lot of positive feedback that my analysis was very convincing, and given that that's one of my strengths, the ability to read the data as I presented here independently and articulate a comparison, I was simply offering that, and that's all I remember.

Q. Okay.

MR. SCHNIEDERS: I'll object and move to strike that last answer as nonresponsive, and, Doctor, if we don't keep it down to -- because I'm running out of time but...

THE WITNESS: I'm sorry that you don't like my answer, but that's my answer.

BY MR. SCHNIEDERS:

Q. I asked you if you were compensated for dinner meetings. I don't think that was responsive.

A. I don't think I've ever been compensated. I don't think I've ever been compensated for a dinner meeting. I don't think I've ever been invited to participate in a dinner meeting.

(Document marked for identification as Toglia Deposition Exhibit No. 21.)

BY MR. SCHNIEDERS:

Q. This is Exhibit 21.

MR. SNELL: I'm reading the transcript where he does say.

BY MR. SCHNIEDERS:

Q. So, anyway, this is Exhibit 22, and this is another e-mail chain and, again, if you look at the very top, it's got Ronald Horton on it again, who we

just saw on that other e-mail regarding the top used KOLs, but down below that, there's an e-mail from a gentleman named Scott Jones.

Do you know Scott Jones?

A. Yes.

MR. SNELL: Counsel, I think you identified this as Exhibit 22, but I think it's 21, just so we get a clear record. You started off on 21 and then you said 22.

MR. SCHNIEDERS: It's 21.

BY MR. SCHNIEDERS:

Q. So under here it says there's a heading that says "Convention Updates," and then it says, "AUGS was another huge success."

Does AUGS have a convention every year?

A. No. AUGS has an annual scientific meeting.

Q. Okay.

A. Understand that industry looks at these things different than how we look at it.

Q. I can believe that.

A. Right.

Q. "The day prior to the official meeting start, we hosted 2 educational events for urogyn

fellows. These events are part of our fellowship education strategy being led by Jen Paradise, and fellow directors are taking of EWHU's involvement." And then the second bullet point or a line point there says, "The Prosima & TVT Exact symposium was well attended and highlights another success led by Dr. Toglia & Dr. Garris."

Do you remember presenting at the Prosima and TVT Exact symposium at AUGS in 2010?

A. I would have presented the TVT Exact module of that. I would not have presented the Prosima.

Q. And you would have been there on behalf of Ethicon, correct?

A. Typically, if I'm remembering the event, I think this was a industry sponsored lunch, and during the lunch hour, they provided lunch for whatever it is, 20 or 30 participants, and I would have given, you know -- as you know, I was involved in the development of TVT Exact, and so I would have provided some kind of an update, you know, or some kind of just general educational talk, as we've provided here.

Q. And you would have been compensated for that, correct?

A. Yes, I would have thought so.

Q. And this was in 2010, which was the year that we saw the e-mail where they say you were paid $153,000, correct?

MR. SNELL: Foundation.

THE WITNESS: I will -- what's the date here? I would say the event occurred in 2010.

(Document marked for identification as Toglia Deposition Exhibit No. 22.)

BY MR. SCHNIEDERS:

Q. I'm going to hand you what I'm marking as Exhibit 22. This is an e-mail from a gentleman named Kevin Frost.

Do you know Kevin Frost?

A. I do not.

Q. The subject is "2011 Incontinence & Pelvic Floor Recap," and then it begins, "Hello all, the 2011 Ethicon Women's Health & Urology Incontinence and Pelvic Floor Summit was recently held in Sonoma, California (March 31-August 2nd)."

Are you familiar with the incontinence and pelvic floor summit that Ethicon would hold annually?

A. Yes.

Q. And was it typically in Sonoma, or did

it move around?

A. No. I only attended a handful of them. This was the only one that I had -- I don't know if they had ever been there before. I had only been to one that was in Sonoma.

Q. Just so we're clear on the record here, if you go back to exhibit -- it's the e-mail that's talking about training around the TVR. You see this one, Doctor, Bates ends with 3824.

What exhibit is that, Doctor?

A. Exhibit 20 is an e-mail from 2009.

Q. Okay. So in Exhibit 20, if you'll see there it says under the subject "RE: thanks TVTR Prof Ed training/summit comments."

Is it possible that when you met Ms. Chaves that that was at the summit?

A. Excuse me?

Q. Is it possible that when you met Ms. Chaves and then wrote this e-mail that was just after the summit?

A. I'm sorry. I thought the summit was 2011. This is 2009.

Q. The summit was every year from my understanding, and you said that you only went to it

periodically, so I'm showing you from 2009, you go down here where it says Dr. Toglia regarding a TVT panel at the summit?

A. Oh, okay. I see. I'm sorry. Yes.

Q. And that's in February of 2009?

A. Yes.

Q. So you would have been there in February of 2009, and then looking at the document we're looking at now, this is 2011, correct?

A. Yes.

Q. And if you go down it says in the middle there a breakdown of this year's attendees are as follows, 31 gyns, 31 urogyns (including 4 fellows), 19 urologists. And then at the very bottom, it says, "a special thanks to the following customers who served as meeting moderators," and it lists you along with three other doctors.

Do you see that?

A. Yes. I'm sorry, there are three more names on the other page. I understand your point.

Q. There are three on this page, and then there's three additional on the other page?

A. Three others besides myself, yes.

Q. And it refers to you as a customer. Do

you know why the company would refer to you as a customer?

A. I don't, because I use their products, perhaps.

Q. At the end of the day they're selling doctors on using the products, not the patient, right?

MR. SNELL: Form, foundation.

MR. SCHNIEDERS: I'll withdraw.

BY MR. SCHNIEDERS:

Q. You see where it says customers, and it's referring to you and some other of your colleagues, correct?

A. Yes. I don't know, but I don't understand why I'm referred to as a customer.

Q. Okay. Set that to the side.

MR. SCHNIEDERS: I'm going to mark this Exhibit as 23.

(Document marked for identification as Toglia Deposition Exhibit No. 23.)

BY MR. SCHNIEDERS:

Q. This will be a very brief question, Doctor, and I just want to call your attention to it. It says under the subject, "Let me know your thoughts... this is a draft." So this e-mail that

we're looking at right here, the second doesn't show that it went to you, but the bottom one down here, the draft itself was a draft of an e-mail to you.

Do you see that?

A. Okay.

Q. And it's from a woman named Rhonda Peebles.

Do you know Rhonda Peebles?

A. Yes.

Q. In that she says, "I am excited to announce that Ethicon Women's Health & Urology received approval for a new TVT sling, Gynecare TVT Exact, and will be launching very quickly. We are putting together 2 key customer events to introduce the product and would love for you to be a part of the launch. You were one of the initial physicians to be exposed to the product via our customer labs last fall so your input would be invaluable."

Do you recall if you attended that event?

A. I don't even know that I ever received this e-mail. I don't think I attended either of those. I don't recall.

Q. Okay. That's fair. Set it aside.

Now, would you consider yourself when you're

working on behalf of Ethicon, not for Ethicon, but on behalf of Ethicon or any other device company to be a salesperson for them?

A. Not at all.

Q. Okay. Are you an advocate for them?

A. I'm an advocate for women's health. I'm an advocate for women that suffer with pelvic floor disorders, and I'm for anything that I can do that helps to increase the awareness of these conditions and treatments for it. As you know, this is a major public health burden, and there are more women that suffer from incontinence and prolapse than we currently have manpower to care for.

Q. Earlier when you were talking about the TVT-R panel that you had been part of, you said you were advocating for that approach because you believe that's the best approach, right?

A. Understand, I was assigned it, right. So if I had been assigned obturator, my assignment was the same and I would have presented my argument in that regard. That said, I'm sure that they chose me for TVT-R because they knew that despite the fact that other products had been developed, despite the fact that I had participated in trials with TVT Secur and

that I taught all three products, that my personal practice was still very much aligned with the retropubic approach, right.

Q. And, similarly, your belief in the TVT product has made you an advocate for it because you believe it's the safest option, right?

A. Well, I believe that the experience and the publications support the safety and the effectiveness of that product and that it is the most vigorous scientific data that we have for any product in the history of incontinence treatment.

Q. But -- and you've advocated for that product and other products you believe in to fellow surgeons when they were talking about it, right?

MR. SNELL: Form.

THE WITNESS: Specifically that product, yes.

BY MR. SCHNIEDERS:

Q. But you would never consider anything that you've done to be advertising for Ethicon, right?

A. No.

MR. SCHNIEDERS: Off the record.

(Brief recess taken at 5:59 p.m.)

(Deposition resumes at 6:02 p.m.)

BY MR. SCHNIEDERS:

Q. We're back on the record after a short break. Doctor, I'm going to mark as Exhibit 24 an e-mail chain.

(Document marked for identification as Toglia Deposition Exhibit No. 24.)

BY MR. SCHNIEDERS:

Q. And this is from, again, Rhonda Peebles, who we just saw an e-mail from her a moment ago, right?

A. Yes. I'm sorry, just reviewing this.

Q. And it's to a Lindsay Froelich.

Do you know her?

A. Do not, no.

Q. All right. It starts off, "Sorry for the delay. I've been swamped with launch meeting planning. Feel free to put time on my calendar the week of the 17th to discuss further, Rhonda."

And this is in response, if you go to the second page, to questions that Ms. Froelich was asking with regard to TVT Exact.

And so she answers several. Under Number 3, a question she's asked is "Is there any clinical data that will be published or presented this year?" And Rhonda Peebles writes back, "There is no specific

clinical data. Exact will leverage data from TVT classic."

Is that an accurate statement, to your mind?

MR. SNELL: Foundation, speculation.

THE WITNESS: I'm sorry, I don't -- I don't see it. Is there two pages?

BY MR. SCHNIEDERS:

Q. There are two pages.

A. Okay.

Q. But it's the front page you need look at. You don't need to go back and forth with the questions. They're written above each spot. So go to the first page.

A. Oh, I'm sorry.

Q. That's okay. If you go to question 3, you will see the question and the answer.

A. Okay. Sure. What's your question?

Q. So the question written there "Is there any clinical data that will be published or presented this year? Answer, there is no specific clinical data. Exact will leverage data from TVT classic."

Do you believe that statement to be true?

A. I'm not aware whether data was -- I'm not aware of data being presented that year.

Q. Okay. When she says "Exact will leverage data from TVT classic," what does that mean to you?

MR. SNELL: Objection to form.

THE WITNESS: How would I know what Ms. Peebles was meaning? I mean, the product is the same. The mesh itself is the same. The modifications that we made to the product is we changed the handle design. We made the trocar thinner. We made the handle disposable. Other than that, there really is no difference. It's sort of -- was sort of a refresh of the product.

BY MR. SCHNIEDERS:

Q. Under question 5, What do you hope to achieve through PR with this program? Answer, increased awareness during the launch phase.

6. What are the important magazines/newsletters you would like to see cover this product? Answer, Urology and OB-GYN throw-away journals.

7. There are major medical meetings -- strike that. 7. Are there major medical meetings where you will be unveiling/displaying this product? And it

lists AUA, AUGS and ICS-IUGA, the advocacy groups, correct?

A. Yes.

Q. And then are any important advocacy groups you'd like to reach at launch? Do you have any relationships with them already? Good question, we should discuss.

And lastly on 9, who do you recommend as internal and external (KOLs) spokespeople for media interviews? Internal, Dr. Aaron Kirkemo.

Do you know Aaron Kirkemo?

A. Dr. Kirkemo was a -- one of the medical directors for Ethicon women's health at the time.

Q. Okay. And then Howard Goldman, the urologist from Cleveland Clinic that we discussed earlier --

A. Yes.

Q. -- that is also one of the authors on the AUGS mesh position statement?

MR. SNELL: Form.

THE WITNESS: Yes.

BY MR. SCHNIEDERS:

Q. And it says, "although the CC may not allow doctors to participate in PR."

A. Yes.

Q. And then lastly it mentions Dr. Marc Toglia, urogyn, Philadelphia.

You see that?

A. Yeah.

Q. Do you recall being approached by Ms. Peebles to be a spokesperson for TVT Exact?

A. Yes, I recall that I was asked to help with an article that addressed urinary incontinence in women, treatment options in women, yes. You understand that, again, I was fairly involved in the development of the TVT Exact product and served as -- I think the video on the surgical steps is myself, you know, demonstrating the procedure, so yes.

MR. SCHNIEDERS: I'm going to mark as Exhibit 25.

(Document marked for identification as Toglia Deposition Exhibit No. 25.)

BY MR. SCHNIEDERS:

Q. This document that is titled "TVT Exact: Editor's Backgrounder (Gynecology).

A. Mm-hmm.

Q. If you look, do you know what a backgrounder is, Doctor?

A. I do not.

Q. Are you familiar with the publication Gynecology?

A. No. I don't think that that was the publication. I think it's the subject.

Q. Do you recall what publication this appeared in?

A. Cosmopolitan, Red Book, I think it was a consumer magazine, Reader's Digest. I honestly -- I vaguely recall that it was a direct-to-consumer thing.

Q. And do you recall that you were the spokesperson within it?

A. I don't think that I would say that I was a spokesperson. I think that I contributed some quotes.

Q. I think it starts off the title is "Gynecare TVT Exact: Building on the Legacy of Gynecare TVT," and it says, according to Marc Toglia, MD, chief of urogynecology for the Main Line Health System in suburban Philadelphia, gynecologic surgeons now have a new option when retropubic placement of a midurethral sling is the treatment of choice in women with stress urinary incontinence. Gynecare TVT Exact.

You see that?

A. Mm-hmm.

Q. It goes on, "Gynecare TVT Exact retains cardinal features of the Gynecare TVT retropubic system, including the laser-cut mesh, protective sheath, trocar geometry, and rigid needle design of the original Gynecare TVT. TVT Exact is engineered with enhancements designed to further reduce tissue and organ damage."

Now, the portion that was already written for you, did you write that?

A. I don't believe so.

MR. SNELL: Form.

BY MR. SCHNIEDERS:

Q. Going on to the next page, about two lines down, I guess on Line 3 it says -- is the next part that I see that you appear in the article, Doctor. It says, Dr. Toglia noted that a good outcome of minimally invasive surgery to place suburethral sling, whether through the retropubic, transobturator, and I'm not even going to get that one. I'll let you read this. Why don't you read this.

A. Well, it's obturator. It's spelled wrong or ischiorectal space, begins with the surgeon's precision and control.

Q. And did you write the passage that your -- this quote from you right here?

A. I don't know. It just says that Dr. Toglia noted, so I may have had a discussion and an interview, and they may have paraphrased me. I honestly don't know.

Q. If you go to the next page at the top, Line 1 it says, "Dr. Toglia observed that there has been a great deal of concern about synthetic meshes. And there's good reason for physicians and patients to exercise due diligence when considering a suburethral sling to treat SUI."

Do you agree with that statement?

A. I was referencing the FDA safety warning at the time.

Q. And, to be fair, that was the FDA safety warning of 2008, correct?

A. I believe so, yes.

Q. So the FDA safety warning of 2011 hadn't come out at that point, right?

A. Sure. I mean, to be fair, I don't see a date, but, you know, I will assume, let's say, for argument sake that this was in the same time frame as when the product was being launched. That would be my

assumption.

Q. I can show you a little bit more specifically.

A. I think we're saying the same thing.

Q. I agree.

A. I don't want to waste anybody's time.

(Document marked for identification as Toglia Deposition Exhibit No. 26.)

BY MR. SCHNIEDERS:

Q. Marking this as Exhibit 26. Doctor, this is another e-mail from Ms. Peebles. I'm sorry. The top of it is an e-mail from Ms. Peebles to someone at a group called idanda.com, something like that, and it says "OB-GYN backgrounder...I'll give you a call," and then underneath it is an e-mail from you to Ms. Peebles.

A. Okay.

Q. And it looks like it says, "Rhonda, here you go," and it appears that at least part of the quote that we just saw in that backgrounder is written right there.

Do you recall if you typed up -- do you recall typing up an e-mail and sending it to Rhonda to give her a quote?

A. I don't recall it, but I think it speaks for itself and, certainly, you know, I'm sort of reading through this, and I'm saying to myself, I never would have said ischiorectal, we don't use that passage, and I obviously read this for factual accuracy and I was responding to her and making suggestions.

Q. And did you notice what you called the subject there when you sent it back to her?

A. TVT ad.

Q. TVT ad?

A. TVT ad.

Q. Is that an advertisement for TVT?

A. I was probably whatever they were -- whatever they were referencing it to me.

Q. Well, I don't -- to be fair, and this is how they produced it to us, and we all know how e-mail works, it usually says re: or forward or something before that if you're just replying. That looks like a subject you picked out?

MR. SNELL: Objection, foundation.

THE WITNESS: Okay. Again, my recollection was there was a short article in some consumer journal. It might have been Reader's Digest. It might have been

Cosmopolitan, you know. I was glad to see them being raising awareness directly to women, you know, telling them that there were treatment options for stress incontinence.

BY MR. SCHNIEDERS:

Q. To be fair, they were only talking about their product, right?

A. I don't know. I mean, I don't know the content of the entire article, but I would not -- I would suspect that they would just talk about theirs. I don't know what the rest of the article entailed.

Q. It's an ad for TVT?

A. I don't know that it's an ad for TVT. I just referred to it as TVT ad. I don't know why I referred to it as TVT ad.

(Document marked for identification as Toglia Deposition Exhibit No. 27.)

BY MR. SCHNIEDERS:

Q. I'm going to mark as Exhibit 27 a spreadsheet that was given to us. Don't worry about the front page. It's extremely hard to read, but we're not going there. It's going to be several pages in.

A. Okay.

Q. So the first page at the top lots like

it says Gynecare Interceed, and obviously it's talking about the barrier product, and then it goes forth, and each page has a different product on it. The product that I want to call attention to is on Page 9631 are the last four numbers of the Bates. It's not perfect, but it's better to read than the other pages.

A. Okay.

Q. At the top you see it says "Gynecare TVT Exact Tension-free Support for Incontinence Roadmap"?

A. Uh-huh.

Q. And then it's got several different categories on the left-hand side that say Strategy, Sales Targeting, Launches, Marketing Tools, Key Messages, Awareness, Contracting/Promotions and Prof Ed Support.

Under "Launches" it says Gynecare TVT Exact, Gynecare TVT Abbrevo launched May 2010 and February 2011 respectively.

You see that?

A. Mm-hmm.

Q. And then under "Marketing Tools" it says Gynecare TVT Exact, and it lists marketing tools on the right-hand side, Gynecare TVT Exact sales aid, Gynecare TVT Exact slim jim, Gynecare TVT Exact procedural

video, Gynecare TVT Exact procedure steps flash card. And then the female patient article featuring Dr. Toglia is listed as a marketing tool.

If you go down to "Awareness," you see that scientific meeting presence, and there's several different advocacy groups that are all going to be presented to, including AUGS, correct?

MR. SNELL: Objection, foundation, advocacy groups.

THE WITNESS: Yeah, I wouldn't use the word advocacy groups. These are professional organizations, but I see what they're saying. I don't have any involvement in that.

(Document marked for identification as Toglia Deposition Exhibit No. 28.)

BY MR. SCHNIEDERS:

Q. I've marked as Exhibit 28 this document, it's titled "Overview," and it's got a paragraph at the top that says on January 30th, 2012 an approved communication (VP of sales & marketing, RBDs, director of communication GPD, PD were briefed on this communication) went out to approximately 300 surgeons who specialize in pelvic surgery (many of whom are faculty for EWHU) notifying them of the following.

Bullet point reads, in 2012, we will continue to facilitate these types of important discussions in a variety of formats but will not be holding a one-time, formal summit meeting. Instead, we plan to utilize other interactive mediums and venues that will allow for more frequent and meaningful dialogue with you and your colleagues.

There was a very loud and emotional response to this notification, which has provided the EWHU organization the opportunity to re-evaluate how we will need to communicate with this group regarding the FAD mesh situation.

See what you've just read there?

A. Yes.

Q. Do you know what the FAD mesh situation is?

A. No.

Q. Okay. This is January 30th of 2012 is what it says, and that's just after the FDA had released their bulletin in 2011, correct?

A. Mm-hmm.

Q. Sorry. I messed up the question, and then you said uh-huh. Was that correct?

A. I'm sorry, that is correct. I mean, I

assume that's yes.

Q. So it's reasonable to say, although we don't know sitting here, but that probably means the FDA mesh situation, because I don't know what FAD means?

A. I don't know that, sir. I don't know that. I can't speak to that.

Q. I appreciate that, but we do know that this is, from a temporal standpoint, just after the FDA released its bulletin, correct?

MR. SNELL: Form.

THE WITNESS: I don't know. All I know is this communicates that a discussion that they were considering not holding another summit.

BY MR. SCHNIEDERS:

Q. And in 2011 the FDA's release is ultimately what precipitated several products being pulled from the market by Ethicon, correct?

MR. SNELL: Lacks foundation.

THE WITNESS: I don't know the relationship between the two, in all honesty. I was not part of that decision.

BY MR. SCHNIEDERS:

Q. And you haven't been provided any documents on that either?

MR. SNELL: Objection, misstates earlier testimony.

THE WITNESS: I don't have an answer for your question.

BY MR. SCHNIEDERS:

Q. So if you go down it says, "Key Takeaways," and it's in bold face-to-face "meetings are being requested by the majority of respondents. They want a forum to vent, share & brainstorm on the future. Lack of understanding on the current situation & EWHU's position needs to be clarified."

Third bullet point, "A feeling that the company is supporting them needs to be delivered. Interactive meetings have a role but second to face-to-face."

Do you recall receiving a communication that would have told you that they were not going to have a summit in 2012?

A. Vaguely.

Q. If you go to the second page, there's a title that says "Feedback from Surgeons."

A. Okay.

Q. And then there are numbers and the first

one is Bob Shull.

Do you know Bob Shull?

A. I do, yes.

Q. Second one is Doug Grier.

Do you know Doug Grier?

A. I do not, no.

Q. And Mike Vardy, then Neena Agarwala and then there you are, Doctor, Marc R. Toglia, M.D., Number 5.

Do you see that?

A. Yes.

Q. And what you've written here is, "Given the current controversies and challenges that we physician are facing with regards to the use of vaginal mesh, I would like to argue that we need this type of meeting now more than ever. The future for vaginal mesh seems somewhat uncertain, however, many of us still believe that it serves a vital, albeit more limited role."

Continues on, "Ethicon's role in providing peer-to-peer support with regards to new and innovative products is what has separated your company from the rest of the field. Ethicon's willingness to partner with and support surgeons in this regard has been

second to none.

I would ask you to reconsider this decision. If cost and travel are a major deterrent, I might suggest that you consider a lower cost venue, such as Philadelphia, or returning to Florida. I am sure that many of us would be willing to sacrifice the bells and whistles to simply get together and meet again."

Did I read that correctly?

A. Yes.

Q. Going back to the first page statement, you wrote, "The future for vaginal mesh seems somewhat uncertain, however, many of us still believe that it serves a vital, albeit more limited role."

What did you mean by "a vital, albeit more limited role"?

A. Well, you know, obviously the FDA's statement was going to be interpreted differently by many people, including people of your profession, sir, and obviously this was going to create challenges really in how we speak to people, you know, patients, women, women that had it implanted previously, people that were currently planning on implanting it.

At the time I don't believe that I was aware of any plans to pull the product. The FDA warning --

yeah, the FDA warning also -- I mean, most of us involved at this level were not aware of the numbers of complications that had been reported to the FDA. I think we were surprised because, according to the literature that we were reading and our own experience, we were not seeing that complications but also the FDA was not very clear. The distinction -- their initial statement seemed to sort of blend stress incontinence with prolapse repair, whereas many of us thought that they were referring specifically to prolapse repair.

And so in the past, the summit meeting was an opportunity to bring people together and foster discussions, and I was pointing out to them that, you know, in that regard, it was still very variable to bring us all together so that we could discuss, you know, how are we going to counsel patients moving forward, how do we counsel patients that have been implanted and are doing well but have concerns. You know, immediately people were saying that there was a recall, when, in fact, there wasn't a recall.

Again, most of us were reading the literature, literature supported that this was a safe procedure with excellent safety and efficacy. Our own experience would support that, mirror that as well. So it seemed

a little bit out of sync.

And, you know, again, Ethicon is based in New Brunswick, New Jersey, which is a stone's throw from Philadelphia. I was just saying to them, look, let's still have this meeting, it could be a quick meeting. You know, let's just get the usual group together, wherever it might be convenient. Again, most of the users, my understanding, were East Coast users. That's why I said Philly or Florida.

Now, I'm sorry, and I apologize, I realize I'm off track. So, yes, as the science has supported, anterior Prolift works extremely well in the anterior vaginal compartment, and the literature states quite clearly that the anatomic results are superior compared to native tissue repair.

Prolift in the posterior compartment, that data was not as robust, and so when I said limited -- vital but limited role, vital meaning the most common problem, the one that causes women the most symptoms is anterior prolapse, and the data and experience clearly demonstrate that this is a safe and effective technique.

So the question in my mind was is that what we concentrate on, do we concentrate on anterior Prolift

as opposed to posterior Prolift. Certainly, those of us that were looking at things from a pooled analysis were reaching the conclusion that the posterior compartment, dyspareunia was a problem with all the repairs. It wasn't clear to us -- it seemed to us that it was similar between the two, although we were getting these reports. So I was just advocating that, and I think it's supported by my report, that at the apex and anteriorly, this was a safe and effective technique in the product, and that's what I meant by vital because that's the most common, the most bothersome, limited, let's concentrate on the anterior and the apex.

Q. What did you mean by "Ethicon's willingness to partner with and support surgeons"?

A. Again, many of us felt there was great value in these summit meetings. I recall that at one or more of these meetings, some of the key inventors of both the TVT and the TVM were brought in from Europe, and we were allowed to listen to them discuss the development of the product. We were able to ask them very clinical questions. So I remember asking one of the TVT individuals who had published on it what do you tell patients when they can return to work and exercise

and stuff like that. So we found the summit to be invaluable as an opportunity for colleagues to get together to further discuss the topic and specifically to listen to experts both nationally and internationally.

Q. But you would agree that it was an uncertain time for mesh, correct?

MR. SNELL: Object, form.

THE WITNESS: I would not agree. I think at the time I think the FDA's mesh message, excuse me, was uncertain because, again, initially they didn't draw -- they didn't -- they said -- I'm sorry. I lost my train of thought.

BY MR. SCHNIEDERS:

Q. The uncertainty you were referring to was what the FDA's position was; is that what you're telling me?

A. It was unclear whether the additional cases reported were sling related cases versus vaginal mesh related cases, as well as what products were involved.

(Document marked for identification as Toglia Deposition Exhibit No. 29.)

BY MR. SCHNIEDERS:

Q. Marking as Exhibit 29 a PowerPoint.

Doctor, do you recall this PowerPoint?

A. I don't know if I ever gave this power point in a meeting or not.

Q. On the second page of the document you see it's titled "The Mesh Story."

Do you see that?

A. Yes.

Q. And it's got your name on it as Director of Urogynecology, Main Line Health System, Philadelphia, PA right?

A. Yes.

Q. Are you familiar with The Mesh Story, was that verbiage you ever used?

A. No.

MR. SNELL: Do you have a date on this document?

MR. SCHNIEDERS: What's that?

MR. SNELL: Do you have a date for this?

MR. SCHNIEDERS: I didn't look, to be honest.

MR. SNELL: That's okay.

BY MR. SCHNIEDERS:

Q. You see on the bottom right-hand corner, it's got Ethicon Women's Health & Urology logo, right?

A. Yes.

Q. We can go off the record, and you can look over that for a second, if you'd like to, Doctor.

MR. SCHNIEDERS: Let's go off the record so he can look at the PowerPoint.

(Brief recess taken at 6:33 p.m.)

(Deposition resumes at 6:34 p.m.)

BY MR. SCHNIEDERS:

Q. Doctor, I think you were saying that you may have worked on this, you're just not sure, right?

A. I don't recognize this.

Q. Okay. But suffice it to say, it's got a Bates number, it was produced to us, and it's titled "The Mesh Story," and it's got your name on it, right?

A. Correct.

Q. It could possibly be one of those slide decks that was made by Ethicon for a presentation they wanted you to give?

A. I would suspect so, yes.

Q. Okay. And, typically, when you would give PowerPoints on behalf of Ethicon, would you do so with Ethicon's logo on it?

A. Typically, I am presenting material prepared by Ethicon in compliance with the FDA regulations, and I would disclose at the beginning that I was up there to speak on behalf of the company to present the company slides.

Q. Okay. And so if you go to the second page, it says "Content."

A. Yes.

Q. And it gives a few things about -- and the context, even though it's not dated, and, frankly, it was my fault for not looking at the Bates number and custodian, but the context would tell us that this has got to be after a recent FDA notice, I suspect; is that fair?

A. I think so. I'm -- I would think that this is after the October 2008.

Q. So you see the content there it says, "What does the FDA notice tell us?" And then "Why is our mesh different?" And is that how you talk in PowerPoints that you give on behalf of Ethicon --

A. No.

Q. -- you say our mesh?

A. No, I have no ownership. I have no ownership. That would be an example of something that

I might strike through and say, you know, you need to be specific that this is Ethicon.

Q. And it says, "How does it work? Why is it designed this way? What does that mean physiologically?"

A. Yes.

Q. Going on to the next page it says "Navigating the Mesh Maze."

Did you ever call it the mesh maze?

A. No.

Q. Bullet point it says, "We have to deal with competing messages surrounding mesh."

Do you agree with that statement?

A. I don't know what that means. I read that as conflicting, but I don't know what that means.

Q. Okay. And it says, "Goal is safe and effective treatment for patients with SUI."

A. Yes.

Q. And it says, "FDA has issued a Public Health Notification warning about risks of mesh."

A. Yes.

Q. "Patients are concerned about mesh implant. We have to help our customers to understand how to minimize their risk."

It says our customers right there. Do you recall from the document we saw before that physicians are referred to internally as customers?

A. Yeah, I don't know that that's what this refers to. Again, I'm quite certain this is not something that I ever presented myself because I would not -- I would never have used the term customer in any form. I not have used the our on the previous page. I would not have used our customers.

This may have been an outline or a markup of something that they were thinking about. I can't tell you I ever saw this. I have no recollection of seeing this. This is certainly not something I've presented.

Q. But fair to say that it says we have to help our customers to understand how to minimize their risk. Fair reading of that is that Ethicon is trying to help doctors that use their products to minimize their risk, right?

MR. SNELL: Foundation.

THE WITNESS: I don't agree, no.

BY MR. SCHNIEDERS:

Q. What do you think it means?

A. I don't know the context, sir.

Q. Okay. Well, that's fair.

A. As a surgeon, I look at this as we need to talk about women and help women to understand and -- I mean, I'm really lost. I'm so sorry. I have no idea.

Q. Does it make you mad that Ethicon put your name on something like this?

A. No. I mean, I don't -- again, this may have been an idea that they floated by me. I don't know.

Q. So the next slide goes on and talks about the FDA alert, October of 2008.

And then the next slide basically breaks down what that alert said, FDA Recommendations, be vigilant for potential adverse events (erosion, infection). Watch for perforation from tools. Inform patients that mesh implantation is permanent and that some complications may require additional surgery that may or may not correct the complication. Inform patients about potential for serious complications affecting QOL, quality of life (dyspareunia, scarring). Provide patient with a written copy of the patient labeling.

Do you provide your patients with written copies of the patient labeling?

A. I think that -- again, I think what

they've done here is they have provided a summary of what the FDA had written. In our practice, we do have readily available each of the FDA safety warnings. We have the position statements from our organization. We have brochures from Ethicon on the TVT, which would include the labeling information. So those are discussed and, when appropriate, offered to the patient.

Q. If you go to the next page it says, "We should be counseling patients differently about mesh. When selecting a sling 'what's left behind' matters more than the delivery system."

What does that mean to you, Doctor?

A. To me what this means, and I think you'll get your answer towards the end of this presentation, is that the majority of the science demonstrating the safety and efficacy of the TVT product is specifically based upon the TVT product. However, other companies that have similar products are sort of borrowing from research that was done on TVT, and so I think what we were speaking to here is the fact that we have a wealth of data on TVT specifically.

And so when we talk to people about sling choices, and, remember, there are 49 slings on the

market or were on the market, what do we tell people, what do we tell, do we tell them we're going to do a sling, we're going to do a synthetic sling, we're specifically using one versus another.

You know, this was -- the use of implants -- we've used implants from the '50s, but it was becoming more commonplace. So as a surgeon, our process for informed consent and discussion was evolving. We all had different methods. When we would go to the summit meeting, different people would say, this is how I present the information, this is how I present the information, this is what I tell the patient, and I think that that's probably what they were -- I think that they were specifically saying, look, we have the data, we've got -- at the time we have 40 some odd clinical trials specifically with our product, whereas competitors may have less than ten products.

Q. And here it says "meshes are different and should be assessed by their own clinical outcomes," which fits in with what you're saying right now, right?

A. Mm-hmm.

Q. And then the fourth category there it says, "In a category of slings where 'Level I Evidence' exists with proven safety and efficacy, why accept a

mesh without outcomes data?"

Level 1 evidence is something that you say quite a bit, right?

A. Yes.

Q. And the next page, "All meshes are not equal." And then it goes on to show the pictures of the different meshes, "All are polypropylene...but meshes have differences."

Do you recall this slide?

A. I mean, this slide has come and gone throughout the history of these discussions as far as specifically how these products are knitted.

Q. And do you believe that AMS or Boston Scientific or Bard's mesh is different than Ethicon's?

MR. SNELL: Form.

THE WITNESS: I don't have much experience using those products. Again -- I just, again, I'm an evidence-based guy, and you can see just clinically my entire experience, I stick with what seems to have the most evidence, so they're all polypropylene, they all are Type I Amid meshes, macroporous. You know, I'm not aware of major differences between them.

BY MR. SCHNIEDERS:

Q. Do you believe that AMS or Boston Scientific or Bard's mesh can cause complications?

A. I don't, no, based upon my extensive review of the literature and the report that I've presented previously. It's not the material.

Q. It goes on it says, "What are the mechanical properties of an ideal sling design?" And it's got four bullet points and tell me if you agree with these, that it "incorporates into tissue."

Do you agree?

A. Sorry. I lost my place.

Q. It's right after the pictures of the mesh. It's titled "What are the mechanical properties of an ideal sling design?"

Do you see it, Doctor?

A. I do. I mean, I believe that these are points for discussion. So, you know, is it important, you know, how a sling incorporates into the tissue, is it important the stiffness, is there a relationship between stiff and non-stiff? These are all the things that we were exploring.

Obviously, we were all comfortable that the introduction of midurethral slings was a major advance

in this field. We were aware of what was being reported to the FDA, so we were saying to ourselves, okay, we're on the front line, let's dig into this. I can't tell you that we drew any direct conclusions, but these were the questions that we were asking.

Q. But, sitting here today, you can't point to those four things as the properties of an ideal sling design?

A. I'm sorry, I mean, yes. Obviously, it is important how the sling incorporates itself into tissue. You know, to me it just speaks to biotolerability, and, yes, that's important as well. Remember that around this period of time there were a couple slings, ObTape, that was taken off the market, had a very, very different design. The original Protogen sling, which is the precursor, was taken off the market. I vaguely remember that somebody had a silicone-coated sling that was not used, you know, after a while. So, again, obviously, these type of things facilitate discussion.

Q. If you go two more slides down, it says, "Gynecare TVT Tension-free Support for Incontinence Mesh: Unique Properties." It says, "Measurable differences from other polypropylene meshes, largest

pore size, lowest stiffness, highest elongation."

Are those important to you as a physician?

A. Again, I did not write this information, you know, what we considered to be important clinically and what the literature supports is that we're using a macroporous product. I mean, is there a difference between 1,100 and 1,300 clinically? I don't believe so. Is there a significance to stiffness? I don't know. Elongation, I don't know either. Is it true that the TVT mesh has the largest pore size? Yes. That it has the lowest stiffness? You know, my recollection, yes. I think those statements are supported by the title. I don't think it speaks to any kind of clinical.

Q. Significance?

A. Application, clinical significance, clinical difference.

Q. Can you go back two pages to the page that looks like the chart like this?

A. Right.

Q. You see there under the asterisk at the bottom it says, AMS mesh was tested without tensioning suture. In another study comparison when measured with the tensioning suture SPARC has a stiffness of

.53 nanograms per milliliter and Gynecare TVT Tension-free Support for Incontinence has a stiffness of .23 nanograms per milliliter. This is a highly significant difference, and it gives a P value there.

You see that?

A. Yes.

Q. So, apparently, it wasn't you, but whoever put this PowerPoint together and put your name on it felt that that was an important difference, right?

A. Well, you know, yes. I mean, there's -- but there's a difference between clinically significant and the fact that -- I mean, that the numbers are highly significant difference. As we go through this, as we had -- as you brought up earlier this afternoon, there was a document that suggested that I participated in a luncheon discussion at a meeting. It may be that this was something that was being considered for that venue. I don't know. I have no recollection that this is actually what I presented, but perhaps there's a relation -- we don't have a date for this.

Q. Finishing up, there's a page that is right before what I've called the footnotes or the credits I guess at the end, it's titled -- it says

"Prolene polypropylene mesh is highly inert."

You see that page, Doctor?

A. Mm-hmm.

Q. And then it says, "treated over 1.5 million patients," and then it says "longest term follow-up of any mesh at 11.5 years," and "The most 'Level I Evidence' with 41 RCTs." Now, that bottom cite, Number 7, if you go over to the references, it says there was a PubMed search, and you can see PubMed search was from 1/26 of '09 through 2/20 of '09, which gives us a time frame for when this would have occurred. I'm assuming you didn't run that PubMed search, right?

A. That is correct.

MR. SCHNIEDERS: Let me take five.

(Brief recess taken at 6:51 p.m.)

(Deposition resumes at 6:57 p.m.)

(Document marked for identification as Toglia Deposition Exhibit No. 30.)

BY MR. SCHNIEDERS:

Q. I have just marked as Exhibit 30 a ProPublica document or it comes from the ProPublica database where you can type in doctors' names and it shows some of the payments they've received from the

past couple of years.

Are you familiar with this type of document?

A. I am, I am.

Q. If you go to the second page, they don't print out very nicely every time, but on the second page it states that from August of 2013 through December of 2014, you received a total of 137 payments for 45,967 -- $45,976.

Does that sound about right to you or sound high, sound low?

A. And, again, not wanting to be argumentative, I take issue with the 137 payments. I think that if somebody brought lunch to my office or to my office staff, that perhaps that might be counted as a payment.

Q. I think, in fact, it is. If you look under down here under types of payments, it's going to tell you exactly what it was.

A. Right. I think also I do recall, and it may not be specifically this time period, that Pfizer had floated a study by me. We submitted the information to the Lankenau Institute of Medical Research. They paid that institute $2,000 for their review of the protocol. We would not participate, but

it was reported as income to me, but I never saw that income.

Q. So I'm going to ask you -- it lists through every single payment here and talks it through.

A. Sure.

Q. I'm not going to ask you about each individual payment.

A. Sure.

Q. I want to highlight or mention the company that's listed just to see if that's something that sounds right, like you would have received something from that company?

A. I mean, I see stuff on here that I clearly had no involvement with, but go ahead.

Q. That's fine, just tell me as we go along.

A. Sure.

MR. SNELL: Note my continuing objection as to the foundation, accuracy of this document, and move motion in limine to preclude this document.

Go ahead.

BY MR. SCHNIEDERS:

Q. Astellas Pharma US, I think we talked

about them earlier; is that right?

A. Yes.

Q. AMS?

A. I'm sorry. The question is specifically is did I?

Q. Do you recall consulting for American Medical Systems Inc.?

A. Yes. Some of them, for example, Elevate is AMS. I never consulted. That is not a consulting thing, $19. That was maybe a lunch, I don't know. I honestly don't know.

Q. Uroplasty, Inc. do you recall that?

A. Yes.

Q. Is Uroplasty, Inc. a device manufacturer?

A. Uroplasty was a device manufacturer. They were renamed Cogentix, C-o-g-e-n-t-i-x, and I consulted with them on productional education slide development.

Q. There were a handful of Ethicon on here. There's one on March 25th of 2014, which is Page 14 of 44 at the top. It says uterine surgery for $107?

A. I'm sorry, where?

Q. If you go to the numbering up here,

Number 14, and it's the top one.

A. I'm sorry. And this was which year?

Q. March 25th of 2014.

A. Got you. I mean, there's probably another physician in my office. At that time there were two other physicians in my practice, and they might have been talking to them about either the morcellator product, that wouldn't be me. That's not something that I would have likely participated in.

Q. And I would note that and consistent with what you said earlier that Astellas seems to be the name that comes up the most often.

Does that sound right to you?

A. Yes, during this time period, probably the work that I did was with overactive bladder having participated in some of the research previously.

Q. Looks like there was food related to a drug called Toviaz from Pfizer.

Do you recall that?

A. Yeah, that's food provided to my office staff. I may or may not have been there.

Q. Same thing with regard to Warner Chilcott for a drug called Enablex?

A. Yes.

Q. Noven Pharmaceuticals for a drug called Brisdelle?

A. That's not me. Brisdelle I believe is a birth control pill. That's not accurate. I never sat in on a lunch for -- no, I'm sorry, Brisdelle, PMS treatment perhaps. Again, probably marketed towards my junior partner. Forteo, not me.

Q. Forteo?

A. No, not me. I have no idea what Xartemis is, never heard of that.

Q. Is that the one that's Mallinckrodt?

A. I have no idea.

Adhesion prevention, I don't recognize that at all.

Q. Allergen for Botox?

A. I've never used Botox. I don't believe that would be myself either. This is not that accurate.

Q. Just so you're aware, for your own sake, you can go and contest anything that's not accurate.

A. I appreciate that. Thank you. Yes.

Q. If you do feel that way.

That's the majority of the companies there.

Lastly, Doctor, when you give a risk-benefit

discussion to any of your female patients about the potential of receiving a TVT device or receiving Gynemesh PS, do you disclose to them that you had a financial relationship with Ethicon?

A. I do.

Q. And what do you tell them?

A. I tell them that I have been involved with professional education, research study, that I've consulted on designs, development of such products. I disclose as much as, you know, they're interested in hearing.

Q. No amounts, I assume, right?

A. I don't tell them specific amounts. Obviously, these are all public records. You can find out how much Medicare paid me last month if you wanted to.

MR. SCHNIEDERS: Doctor, I think my time is up. I have no further questions. Thank you for your time.

BY MR. SNELL:

Q. Doctor, I'm just going to ask a few follow-up questions on a couple topics.

Doctor, I'll represent to you that depositions of the plaintiffs' experts are ongoing. I know you've

been provided Dr. Ostergard's deposition, but there are many other depositions going on, and it will be, I'll represent, sent to you.

Could you plan to reserve the right to issue any new or updated opinions based on depositions of the plaintiffs' experts?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I would say that sounds fair.

BY MR. SNELL:

Q. And will you look at any new studies that come out that you may or may not find to be pertinent to your opinions?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I read this literature frequently so...

BY MR. SNELL:

Q. You were asked questions about if you were provided company documents. Besides the IFUs, the professional education materials, the slide decks, the videos and all the stuff that are on the thumb drive somewhere that we're going to put in the box as Exhibit 4, I just want to call to your attention. So in Dr. Ostergard's materials that were provided to you,

are there company documents and things of that nature as well?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: I mean, obviously, the Prolift documents, these are slides on Prolift, so, yes. There are various e-mails.

BY MR. SNELL:

Q. You were asked about your expertise in various areas. Let me ask you about that.

Do you believe you're an expert in how the chemical polypropylene the polymer performs in pelvic surgery in a woman?

MR. SCHNIEDERS: Object to form.

THE WITNESS: Yes, I do believe I'm an expert in that.

BY MR. SCHNIEDERS:

Q. Besides, obviously, your testimony that you've utilized polypropylene over many decades before pelvic surgery, have you also researched that topic in the reliable scientific medical literature?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I have.

BY MR. SNELL:

Q. Have you analyzed the design of the

devices that utilize the Ethicon polypropylene?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I have.

BY MR. SNELL:

Q. You were asked if you're an expert in polymer chemistry. Do you believe you're an expert in that field?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: As it pertains to what we're discussing here and its intended use, yes, I am.

BY MR. SNELL:

Q. And before you even went to medical school, I think you testified you have a degree in biochemistry as well?

A. Correct.

Q. Do you believe you have a very good working knowledge and understanding of chemistry?

A. Yes, I have.

Q. Including the chemistry of polypropylene and what -- the atoms or molecules it's made up of?

A. That's correct. I did research as an undergraduate in silastic plastic delivery systems.

Q. You talked some in this deposition about

your consulting and evaluation of the development and design of sling and prolapse devices.

In your earlier deposition, you recall covering that subject as well?

A. I do, yes.

Q. Do you stand by your testimony from your earlier deposition in the Mullens case about the various design and development work you did?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I believe we covered that pretty extensively.

BY MR. SNELL:

Q. Do you recollect in that testimony you discussed that you were involved in the design validation of the Gynemesh M mesh?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes.

BY MR. SNELL:

Q. And is that a prolapse mesh similar to Gynemesh PS?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes.

BY MR. SNELL:

Q. Do you recollect testifying and telling

the lawyers under oath that in your role as being one of the design validation surgeons, you assessed the suitability, safety, efficacy and adequacy of the design of that product?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: I did, yes.

BY MR. SNELL:

Q. Do you also recall and recollect your testimony that in the design validation activities you performed on the prolapse mesh for Ethicon, you also assessed the instructions for use as to its adequacy and clarity and how it laid out instructions?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I did.

BY MR. SNELL:

Q. Do you recollect that you testified that in connection with your evaluation of the IFU for the prolapse device, you were asked whether it was clear or cohesive or accurate?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I did.

BY MR. SNELL:

Q. And besides the prolapse mesh, I think you testified here today and you testified earlier, you

have consulted and evaluated the design of other Ethicon pelvic floor products over various time periods?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I have.

BY MR. SNELL:

Q. For example, you testified about your design evaluation and your work with the TVT Exact product for stress urinary incontinence?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, starting from the concept of the design all the way through the engineering, all the way through the suitability of the product and the professional education component of that, which included the teaching, the filming of the video demonstrating the technique.

BY MR. SNELL:

Q. And would that professional education also include the instructions for use?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, it did include the instructions for use.

BY MR. SNELL:

Q. And so do you believe you're an expert and qualified to opine on the adequacy of the instructions for use for the Gynemesh PS and Prolift and the TVT product?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I will agree with that.

BY MR. SNELL:

Q. And did you actually teach the IFU during your professional education activities for various products in addition to the discussions or I think you called them proctorships as well?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I did.

BY MR. SNELL:

Q. And I think we've seen or you produced earlier, as I recall, slide decks, maybe more than one. Do you recollect during your professional education activities talking to pelvic floor surgeons about the potential risk and how to utilize and insert these devices?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes. We specifically would go over techniques, strategies to

minimize, strategies to recognize the potential.

BY MR. SNELL:

Q. You were asked about the TVT Secur randomized control trial.

Do you recollect that?

A. I was asked about the security trial, which compared TVT retropubic with TVT Secur.

Q. Was your site paid by Ethicon? I just want to understand, because I think there was questioning about that, and I got a little unclear.

A. I understand.

MR. SCHNIEDERS: Object to the form.

THE WITNESS: My recollection is that we were paid by the Cleveland Clinic. I might have earlier mentioned that the money came from the foundation, but I do believe that the actual payments came through the Cleveland Clinic Foundation.

BY MR. SNELL:

Q. You were asked questions about whether you were an expert in pathology. Let me ask you this: In your review of the medical literature, have you reviewed the pathology papers with the

photomicrographs, such as the Clave study?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I've reviewed the studies as we've listed them involving the scanning electron microscopy using the Fournier method of analysis, the optical method of analysis as well, the histologic -- several histologic studies.

BY MR. SNELL:

Q. And based upon your medical education and training, were you able to adequately evaluate those pathologic studies?

MR. SCHNIEDERS: Object to the form.

THE WITNESS: Yes, I think I have an excellent working knowledge of those topics.

MR. SNELL: That's all I have. Thank you for your time.

(Witness excused.)

(Deposition concluded at 7:17 p.m.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I, MARC R. TOGLIA, M.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MARC R. TOGLIA, M.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2016.

My commission expires:_____

_____

Notary Public